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The DRUG MAKERS and The DRUG DISTRIBUTORS

TASK FORCE ON
PRESCRIPTION DRUGS

Background Papers

OFFICE OF THE SECRETARY • U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

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and
The DRUG DISTRIBUTORS

December 1968

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TERMINOLOGY

The term *generic equivalents* is not used in the body of this report. Although it has been widely utilized, it has been given so many different interpretations that it has become confusing. Instead, the following terms are used:

Chemical equivalents—Those multiple-source drug products which contain essentially identical amounts of the identical active ingredients, in identical dosage forms, and which meet existing physicochemical standards in the official compendia.

Biological equivalents—Those chemical equivalents which, when administered in the same amounts, will provide essentially the same biological or physiological availability, as measured by blood levels, etc.

Clinical equivalents—Those chemical equivalents which, when administered in the same amounts, will provide essentially the same therapeutic effect as measured by the control of a symptom or a disease.

The following terms are also used:

Generic name—The *established* or *official* name given to a drug or drug product.

Brand name—The registered trademark name given to a specific drug product by its manufacturer.

Molecular manipulation—A minor modification in the molecular structure of a chemical, yielding a new and patentable product which may or may not offer a significant therapeutic advantage over a related drug already on the market.

"Me-too" or "duplicative" drug—A new drug, often made by means of molecular manipulation, which offers no significant therapeutic advantage over a related drug already on the market. (Chemical equivalents, since they are chemically identical, are not considered to be "me-too" products.)

Rational prescribing—Prescribing the right drug for the right patient, at the right time, in the right amounts, and with due consideration of relative costs.

INTRODUCTION

IN MAY OF 1967, acting upon a directive from the President, John W. Gardner—then Secretary of Health, Education, and Welfare—established the Task Force on Prescription Drugs. The charge to the Task Force appeared to be simple—

> *Undertake a comprehensive study of the problems of including the cost of prescription drugs under Medicare.*

Few assignments, however, have been more complex. Essential for the Task Force study was objective information on the health needs and resources of the elderly; the present patterns of drug use; the nature of drug research, production, and distribution; current drug insurance programs in the United States and abroad; reimbursement methods and administrative approaches; legal and fiscal aspects; and the pharmacological and clinical aspects, including the intricate problem of chemical and clinical equivalency of generic products.

In some instances, the necessary data were readily available. In others, they were not—and the Task Force found it necessary to undertake its own special research projects.

The information derived from these studies serves as the basis for the findings and recommendations which are being published separately by the Task Force. In addition, however, this basic material appears to have great value for the Congress, many State and Federal governmental agencies, the medical and pharmacy communities, the drug industry, health insurance organizations, health educators, and consumer groups. Accordingly, the Task Force is publishing the detailed results of its studies in a series of background papers.

This volume, combining studies on the manufacture and the distribution of prescription drugs, is one such publication. It was prepared by the Task Force staff in cooperation with many consultants, both governmental and nongovernmental, whose invaluable assistance is gratefully acknowledged. Special appreciation goes to the many representatives of the pharmaceutical industry, the pharmacy profession, and the medical and scientific communities who kindly made available much unpublished material to the Task Force and provided their valuable advice, guidance, and proposals to the Task Force staff.

It is evident that the present high quality of health care enjoyed by most Americans—though by no means by all of them—is a testimonial in considerable part to the many accomplishments of the American drug industry and the American pharmacist. But it is also clear that the level of health care in this country is not yet high enough to justify any complacency or slackening of our efforts. Serious problems still exist in the development and marketing of drugs, and realistic steps must be taken—with imagination, understanding, courage, and boldness—if our goals are to be achieved. The nature of some of these problems and the steps that can be taken are indicated in this volume.

Philip R. L

PHILIP R. LEE, M.D.

PART A

THE DRUG MAKERS

FOREWORD

DURING the past 10 years, the American drug industry has been attacked and denounced perhaps more vociferously than any other industrial group in this country. In Congressional hearings, and in newspaper and magazine articles, both its motives and its methods have been heavily criticized. At the same time, it has been vigorously defended, with detailed descriptions of its many contributions to the health of mankind, and with emphatic claims concerning the reasonableness of its profits.

This controversy and debate apparently stem from many factors, some that relate to the nature of the industry itself and some to the nature of the economic, medical, social, and political environment in which it functions.

Certainly an important part has been played by the spectacular financial success that accompanies an accelerating sequence of the industry's scientific achievements. The growth of its major firms into the ranks of "big business" undoubtedly contributed to this situation, as did the changing nature of competition in the industry, and the widely-publicized acceleration of its research and development activities.

At the same time, other forces were at work. There was a dramatic growth in concern for the quality of human life, marked by the advent of the Federal government as a significant financer of health care, a continuing expansion of governmental and nongovernmental health insurance programs, and new interest in public health and in the problems of the economically-deprived and the elderly. There are a steadily mounting interest of the public in the new and exciting scientific discoveries, and an intense desire to benefit from them. There were strict new regulatory laws—and widely-reported Congressional investigations which led to their enactment. And there was an unprecedented skyrocketing in the cost of total medical care.

All of these, and perhaps many other factors, combined to draw attention to the sources of supply, not only of drugs, but of all medical and health-related goods and services—to the advances made in improving and expanding the quality and quantity of these goods and services—and, of special importance in a market economy, to the efficiency, reasonableness, and fairness with which these essential commodities were distributed.

Here the production and distribution of drugs invite particular examination.

CHAPTER 1

HISTORY

Although drug manufacturing as a distinct and separate industry is a fairly recent development in man's history, drug making and drug taking are among his oldest activities.

As far back as two millennia before Christ, man used magic formulae and the natural substances in his environment to purge himself of disease demons, or *drogues*. The *magi*—Persia's priest-physicians—gathered herbs and used insects and parts of animal bodies to treat their patients. Incantations and faith in the supernatural properties of earth, fire, and water were as important to early healers as was their rudimentary knowledge of the human organism. In fact, the Rx sign on a prescription is said by some to have originated as a prayer to Horus, the Egyptian god of healing, or possibly as an abbreviation for the Latin words "Take thou."

In ancient Greece, Herophilus is said to have called drugs "the hands of gods," and the word for today's pharmacy—*pharmakon*—originated in the Greek term for administering drugs.

Eventually, there came a separation between drug making and drug administering. About A.D. 754, on orders from the Caliph of Baghdad, what was probably the world's first apothecary shop was established in the ancient city.

By the Middle Ages, the distinction became even more clear. The physician believed he possessed the ability to select the appropriate drugs in appropriate proportions to treat patients. He was thus distinguished from the apothecary, who supposedly knew drugs but not man.

Thereafter, the two professions continued on separate and presumably cooperative courses, although there were periods when the physician-pharmacist-patient relationship was at least somewhat confused. Around the middle of the 19th century, for example, the situation could be best described as chaotic. Laymen distrusted medicine, though not necessarily drugs—especially the botanicals. Doctors defended medicine in one form or another, but they had developed an increasing skepticism toward the therapeutic efficacy of such agents. In medical practice, though, it was admitted that drugs had to be prescribed "because of the superstition of the patient and to strengthen his confidence." (*75*)

Drugs in America

Although apothecary shops came to the New World from Europe as early as 1748, this country's first manufacturing pharmaceutical laboratory was opened to supply medicines for General Washington's army in 1778. Pharmaceutical houses expanded vigorously during the Civil War, and distribution of drugs soon became national in scope.

The first major crisis to challenge this growing industry came in World War I, when it became obvious that the United States was almost completely dependent upon Germany for many of the new and potent synthetic drugs developed by German drug manufacturers. The war shut off the importation of these materials, and American physicians found themselves deprived of drugs essential for their practice. Accordingly, American firms plunged into the task of synthetic drug production.

Until World War II, these companies introduced relatively few innovations of their own making and provided only modest support for original research in this field. But after Pearl Harbor, the American drug industry underwent almost explosive growth, and today it leads all nations in drug research, development, production, and distribution.

This postwar period witnessed the solid establishment of the philosophy that enough research and development, properly directed, would provide the key to finding new and better drugs, with full implications for both the therapeutic and economic benefits to be gained therefrom.

Appreciation of this unprecedented growth requires consideration of the various types of companies which were involved.

The Drug Industries

The term "drug industry" is imprecise, including in its broadest usage such activities as both the manufacturing of the bulk chemicals that are the active ingredients in drug products and participation in the various stages of manufacturing and marketing of finished, dosage-form pharmaceutical preparations containing those ingredients.

Actually the term "drug industry" includes three separate industries—the medicinal chemicals industry, which produces bulk active ingredients (sometimes called "fine chemicals"); the biological products industry; and the pharmaceutical preparations industry, which includes those firms engaged in the manufacture and distribution of dosage-form drug products. It is the manufacture and sale of finished products that has attracted much of the attention directed toward the drug industry.

In the realm of pharmaceutical preparations are proprietary drug products, the common household drug products promoted directly to the consumer; and ethical drug products, so-called because they are promoted to the medical profession rather than to the ultimate consumer. Ethical drugs, in turn, are of two types: *prescription drug products*, which include such items as hormones, tranquilizers, most antibiotics, and sedatives; and *over-the-counter drug products*, which may be sold without a prescription but usually are recommended by physicians and hence are advertised directly to them. While the distinctions between these categories are often blurred, perhaps the most meaningful separation is that of *prescription drug products* from *nonprescription drug products*. Of all of these many facets of the drug industry, that which has the most relevance to the controversies surrounding the industry's operation is the manufacture and sale of prescription drug products.

The Drug Companies

The firms engaged in the manufacture of prescription drugs are as varied in background, activities, size, scope, composition, and function as are the products which they sell.

There are firms which came to prescription drug manufacturing from the laboratories of physicians who started producing drug products first for themselves and later for other physicians; others that came from retail pharmacies which moved into wholesale manufacturing; others which came from chemical firms that moved into the manufacture of finished-form products; and still others which came from the distilling or meat packing or other industries related in one way or another to drug manufacturing techniques or sources of supply.

The Old-Line Companies. After the Civil War and before World War II, the pharmaceutical industry was scientifically active and economically prosperous but hardly a pacesetter among the burgeoning consumer product industries of the time.

"On top of the list," it was noted, "were the old-line ethical drug houses that dispensed a broad line of prescription drugs. They were, for the most part, family owned or controlled. Conservative and steeped in tradition, they put great emphasis on public responsibility, product quality, and close association with physicians. These segments of the industry, in fact, gave the industry many of the aspects of an exclusive gentlemen's club."(*35*)

The old-line companies generally bought medicinal chemicals, plants, and extracts in bulk form and processed them into drugs for sale to physicians, hospitals, and retail pharmacists. The pharmacists themselves often compounded these drugs into the medicines prescribed by their customers' physicians.

Bulk Producers. Closely allied to the prescription drug companies, although distinct in ownership and operation, were the chemical firms which manufactured bulk drugs. Their products were sold to the prescription drug houses for processing, rather than the manufacturer himself processing them into finished medicinals.

Proprietary Producers. Another group, largely separate from the prescription drug houses, were proprietary or nonprescription drug companies which produced headache pills, cold remedies, laxatives, liniments, and a host of other household standbys. Their output at one time accounted for more than half of the drug industry's total volume. A few firms had significant investments in both prescription and nonprescription drug products.

Industry Expansion

Slow but steady progress toward the chemical breakthroughs that were to come in the 1950's characterized the U.S. pharmaceutical industry up to World War II. Figures alone reveal the scope of the industry's remarkable expansion. Drug sales at the manufacturer's level in 1939 barely exceeded $300 million. Eighteen years later the figure was climbing well above $2 billion, and in another decade had reached nearly $5 billion. In prescription drugs, the last 10 years have witnessed a rising curve of domestic sales of dosage form drugs for human use from just short of $2 billion in 1958 to an estimated $3.2 billion in 1967,[a] and sales of prescription drugs have outpaced those of nonprescription drugs (Figure 1).

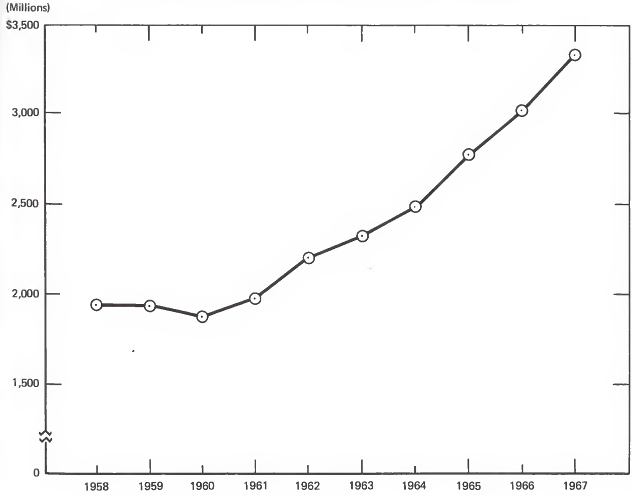
Sales increases in the prescription drug market have resulted as much from broadening the effects of medications into such areas as family planning—the "pill"—as from product displacement by more effective or less costly drug products.

As today, there existed before World War II more than 1,000 small drug companies whose business was limited to specialty or regional markets. And, as in the 1960's, these companies accounted for a relatively small part of the prescription drug business. The major producers of prescription drugs—about 80 companies—are all members of the Pharmaceutical Manufacturers Association (PMA).

PMA is a voluntary nonprofit organization composed of 136 companies which account for upwards of 95 percent of the prescription drugs sold in the United States.

PMA was founded in 1958 and is the successor of two earlier organizations founded respectively in 1912 and 1913: the American Association of Pharmaceutical Chemists (later renamed the

Figure 1.—Domestic Sales of Prescription Drugs for Human Use



SOURCE: ESTIMATES BY PHARMACEUTICAL MANUFACTURERS ASSOCIATION, 1958–1968

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[a] See also pp. 9–12.

American Pharmaceutical Manufacturers Association), and the National Association of Manufacturers of Medicinal Products (later known as the American Drug Manufacturers Association).

The four principal stated objectives of PMA are (1) to encourage consistently high standards of quality in pharmaceutical products; (2) to encourage research toward development of new and better medical products, facilities, and methods; (3) to disseminate information to and on behalf of the industry; and (4) to work with others for the advancement of medical science. (*58*)

In May 1965, the organization established the Pharmaceutical Manufacturers Association Foundation, Inc., to "promote the betterment of public health through scientific and medical research . . ." (*61*)

The PMA is known primarily for its trade promotion, public relations, and other trade association activities. It is, in fact, the major lobbying organization of the drug industry, and it and some members of its staff are registered as legislative advocates with the Congress.

Although there are no formal organizational relationships between PMA and organized medicine, many of the functions of the AMA and other national, State, and local medical groups are financed to a very large degree by PMA member companies through advertising in medical journals, commercial exhibits at their medical conventions, and other activities.

Impact of the "Wonder" Drugs. The coming of an array of the so-called wonder drugs was anticipated by development of the sulfa-drugs in the 1930's, and was further heralded during World War II with the introduction of penicillin. The wonder drugs—generally considered to be specific chemicals for the treatment of specific infections and other diseases—were responsible for major scientific and economic changes in the drug industry.

At this point, some of the industry's chemical suppliers found that increased sales and greater profits could be realized by turning their own bulk materials into finished products. They also found that some of their former bulk sales customers—the old-line prescription drug firms—had started to produce at least some materials for themselves. Many of the large nonprescription drug firms, meanwhile, also were attracted by the potential for growth and the money to be earned in the prescription drug business.

Change in Directions. More systematic research and development, and more aggressive marketing practices, were hallmarks of the new competition. Both the newcomers and some of the moderately large specialty drug houses were increasingly willing to invest large sums in research, seeking the rewards in an array of profitable new chemicals—steroids, tranquilizers, and broad-spectrum antibiotics among them. Not only were new markets created but many familiar old products were displaced or became obsolete.

Some of these firms became so-called full-line companies, with a large array of pharmaceutical products for both human and animal use, while what are called short-line companies specialized in a relatively limited list of drugs, most of them manufactured for human use only.

Drug innovators were anxious to recoup research outlays quickly because of the growing risk of product obsolescence. As the pace of product innovation quickened, producers attempted to capture a share of the market as soon as possible, and to create new markets.

"They deluged physicians with blitz sales campaigns and intense promotion," according to one chemical industry writer. "By these means, some of the smaller and newer drug firms carved out for themselves a big segment of the overall market." (*35*, p. 73)

Prescription drugs are peculiarly adapted to such aggressive marketing. Promotion can be focused narrowly on a small, homogeneous target group of about 200,000 practicing physicians and even more closely when aimed only at specialists.

The situation here is unusual. The physician who selects and orders a drug product is not the consumer who pays for it, and the consumer has little or no voice in the selection—a marketing situation almost unparalleled in other consumer industries.

Furthermore, once the producer has established the value of his product and his own integrity and reputation in the mind of the doctor, he has not only a firm grip on the market for his present products but also an entree for future products. Manufacturer identification is a two-edged sword, of course. The doctor can deny the drug maker a part of the market if a product is disappointing; the doctor's dissatisfaction may extend to other products as well.

The climate for prescription drug making still is changing. The influence of government programs—both of the regulatory and Medicare types—has markedly affected the drug industry in the 1960's. Fewer new products have been approved by the government for marketing following 1955, and since 1963 those that are marketed must pass more rigorous animal and human tests. Medicare and Medicaid programs have created the distinct possibility that an increasingly large share of the future drug market will be partially supported by taxes. In this prospect, there are implications for industry profit levels which are under intensive study both in and out of government.

These factors have had some influence on a trend toward diversification by many large pharmaceutical firms. But in today's economy, diversification appears to make good business sense for a number of industries. Veterinary and agricultural products—natural avenues of diversification—already make up significant shares of several full-line company markets. Companies manufacturing medical instruments and biomedical devices have been purchased by some specialty drug firms. A growing number of drug companies are moving into or broadening their lines of proprietary drugs and household products. A few that formerly made only prescription drugs have established divisions which produce cosmetics, toiletries, plastics, and even food products. At the same time, some nondrug companies are diversifying by moving into the prescription drug area.

One principal distinction among drug companies today is whether or not they engage in original pharmacological research and new product development. As diversification continues, and research costs increase in relation to productivity, the number of independent short-line specialty houses may decline—mostly because of acquisitions by broad-line companies and corporate mergers. However, increasing demand for existing prescription products and even some nonprescription items—a demand generated to a considerable extent by growing government programs—may encourage the large, diversified companies to expand their pharmaceutical lines.

Search for a Safe Drug. Even as their industry exhibits dynamic growth and change, drug makers are beset by a public misconception that reaches into the halls of Congress: that complete safety with drugs can be achieved. It cannot.

It must be emphasized that no drug, or any other biologically-active agent, can be absolutely safe. There is no known compound which, under certain conditions, cannot injure, destroy tissue, or cause death. Accordingly, the goal is the development of drugs with a high *relative* degree of safety. Further, despite the most rigorous drug testing procedures devised by the medical community, the manufacturers, and the Federal government, there is always the possibility that something will be overlooked. Sometimes, only mass use over long periods will bring all of a drug's dangers (or all of its benefits) to light, and basic research in clinical pharmacology continues to raise questions about the possible toxicity of even the most common drugs. (*15*)

The decision to prescribe a drug—or the decision not to prescribe—cannot be based merely on the harm the medicine may do. The nature of the disease and its severity—as well as the patient's wishes—must be taken into account. All doctors are instructed in their student days "first to do no needless harm." But until pharmacology becomes a more sophisticated science, carrying out the letter of this axiom is vulnerable to unexpected complications.

It is recognized, in the view of one writer, that past mistakes in regard to adverse drug reactions cannot be undone. But he says each party involved should reconsider his position, in the following manner:

> "The public, by not expecting the impossible; the manufacturer, by making greater efforts to teach instead of promote; and the physician, by realizing that modern drug therapy is an experiment in which each patient requires careful supervision, and in which the drug and its dosage must be adjusted to individual response." (*15*, p. 54)

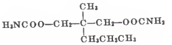
CHAPTER 2

DEFINITIONS

For an understanding of the following sections, it is necessary to specify the three names—*chemical*, *generic* and *brand*—which may be used to identify a drug.

Chemical Name

A drug's *chemical name* is descriptive of its chemical structure—based on rules of standard chemical nomenclature—such as the tranquilizer with the chemical name 2-methyl-2-propyl-1, 3-propanediol dicarbamate. While long and cumbersome, this name is also precise, for it serves as a complete identification of the compound to any trained chemist. It is related to the chemical formula of the particular drug—



$$\mathrm{H_2NCOO{-}CH_2{-}\overset{CH_3}{\underset{CH_2CH_2CH_3}{C}}{-}CH_2{-}OOCNH_2}$$

Generic Name

Drugs also have a shorter, more simple, established or *generic name*. This may or may not be an abbreviated form of the chemical name. It is the name most commonly used in the scientific literature, and by which many physicians and pharmacists learn about a particular drug product in professional school. Thus, the tranquilizer described by chemical name above is known *generically* as meprobamate.

Brand Name

Companies frequently give their drug products a brand name, or trademark name, to distinguish them from competitive products which may be identical insofar as active ingredients are concerned. A firm which has a patent on a particular drug product would, of course, register a brand name, or trade name, to protect its unique market. Even after the patent expires, the brand name would be retained because promotional efforts over the years probably would have established a place for the product in the minds of the physician and the pharmacist.

There are no official rules controlling brand names. The objective is to coin a name which is "useful, dignified, easily remembered, and individual or proprietary," according to the Pharmaceutical Manufacturers Association. (*55*, p. 4)

Thus, in the example described above by *chemical* and *generic* name, the tranquilizer carries different *brand* names: Miltown in one company's inventory, and Equanil in another's.

CHAPTER 3

INDUSTRY AND MARKET STRUCTURE

Prescription drugs have spearheaded the upward economic thrust of the pharmaceutical industry since World War II. Nonprescription drug products still make up a large part of the industry's total sales volume, and nondrug products are becoming more important in expansion plans, but it is in the highly competitive area of chemical tools designed to help the physician treat his patient that the industry has prospered most.

"Perhaps," as a magazine writer paraphrased in 1964, "no industry of similar size offers so much to so many as does the drug industry." (*35*, p. 69)

Number of Companies

The "industry," in this context, consists substantially of the 111 firms and their 25 associated subsidiaries that are members of the Pharmaceutical Manufacturers Association; these firms have accounted for most of the significant drug developments in the last generation; their sales—ranging from $200,000 annually to over $100 million apiece—account for about 95 percent of the American prescription market, with about 30 firms accounting for three-fourths of this share. Included in this select group are the U.S. subsidiaries of foreign-owned firms, which may account for 10 to 15 percent of all domestic dosage form sales. (*61*)

Individual drug markets or therapeutic classes tend to show higher sales concentration than does the industry as a whole, since many firms tend to specialize in a limited number of therapeutic areas, such as the production of antibiotics, tranquilizers, or corticosteroids. Accordingly, a large portion of sales in a sizeable number of product categories is achieved by a small number of firms that specialize in those respective categories.

The drug production of some 750 additional, generally smaller companies also is of considerable importance. Operating frequently on an intrastate or regional level, often concentrating on relatively few kinds of drugs and selling them primarily to government agencies or institutions, their operations tend to be obscured in discussions of the industry. The National Association of Pharmaceutical Manufacturers, representing about 150 such firms, reports that member company sales range from less than $1 million each per year to perhaps $10 million, not all in prescription drugs. While generally assumed to be generic-name drug producers, many of these firms market their products under brand names. Some are drug manufacturers in the broad sense, but many are essentially repackagers or finishers, obtaining bulk supplies from larger American or foreign firms. Some conduct pharmaceutical research and hold patents on their work, though such instances are exceptional.

Number of Employees

Manufacturing sources reported in 1967 that pharmaceutical company employment here and abroad totaled 205,800, of whom 125,000 were employed in the United States. Drug industry employment has risen 45 percent since 1950. (*57*)

Among prescription drug workers, a high percentage are scientists and technical specialists. Production employees comprise about 38 percent of the domestic working force.

In 1967, drug industry workers in the United States were employed in approximately 1,600 locations. Main producing areas were the Middle West, Middle Atlantic, and East North Central States. The larger drug firms currently have facilities in 44 States.

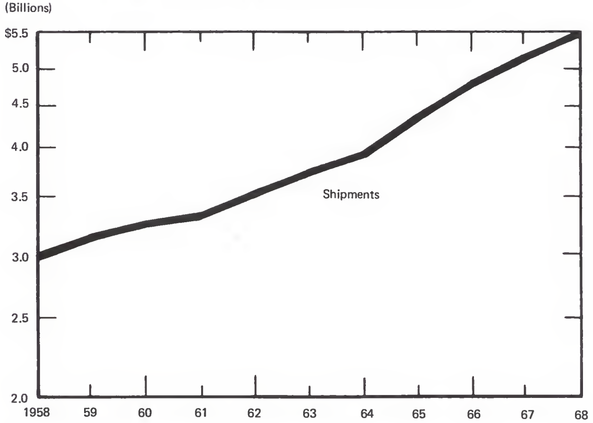
The industry's annual payroll in the United States is nearly $900 million, and it pays taxes of approximately $506 million per year to Federal, State, and local governments. (*71*, p. 1416)

Value of Products

According to government sources, drug manufacturers' shipments of both prescription and nonprescription products are expected to reach a new high of $5.5 billion in 1968, up 6.4 percent over 1967's $5.1 billion and 13.2 percent above 1966 shipments of $4.8 billion. (*81*, p. 135) The value of drug industry products of all types has shown a steady increase each year since 1958, when the total was placed at $3.0 billion. Figure 2 shows the continuing ascent of drug industry shipments of all types, not drug products alone.

327-512 O—68——2

Figure 2.—U.S. Drug Industry Shipments, 1958–1968



SOURCE: U.S. DEPARTMENT OF COMMERCE: U.S. INDUSTRIAL OUTLOOK 1968, DECEMBER 1967, p. 135.

In 1967, 15 prescription drug makers had combined sales of almost $2.8 billion, and total after-taxes income of $362.4 million. Another nine companies—all with widely-diversified product lines—accounted for $1.7 billion in worldwide drug sales. The increase in their pharmaceutical sales—as a share of total company sales—has ranged from 41 percent to 164 percent in the last five years. (*17*, pp. 6–7)

Prescription Drug Sales

In 1960, domestic sales of prescription drugs in dosage form for human use were $1.9 billion; by 1967, sales had grown to an estimated $3.2 billion. Between 1957 and 1966, the pharmaceutical industry's output grew 10 percent faster than did the national output of all goods and services (gross national product). (*59*, p. 8)

Studies of the prescription market shares of 33 leading drug firms, conducted for the PMA, revealed that in 1966 the five largest selling firms accounted for 30.2 percent of the total sales of the group, down from 37.7 percent in 1960 and 40.5 percent in 1959. The highest individual volume among the five in 1966 was 6.7 percent, compared with 8.1 percent in 1960, and 12.7 percent in 1950. The data in these studies did not include hospital and government sales, except for 1966.

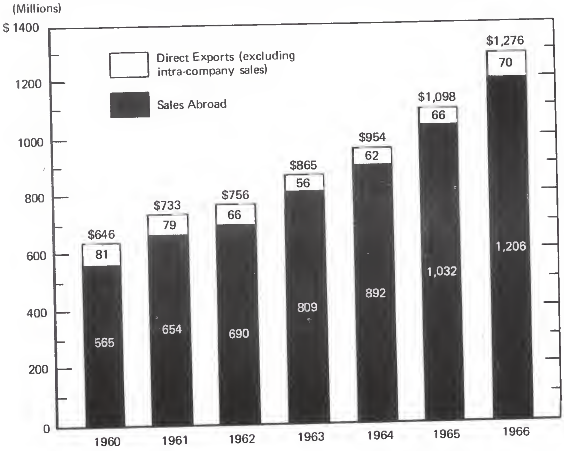
The bulk of the remaining domestic prescription drug market in 1966—69.8 percent—was shared by fewer than 30 other companies included in the study; in 1960, the five leaders left 62.3 percent of the market to other companies, and 50.9 percent in 1959. (*59*, pp. 21–22)

Foreign Operations

Much of the recent growth of the U.S. drug industry has been in the international sector, resulting mainly from the expansion of domestically-owned foreign facilities.

Sales of all types of pharmaceutical preparations in foreign countries by U.S. firms increased

Figure 3.—Prescription Drug Foreign Sales by U.S. Manufacturers



SOURCE: PHARMACEUTICAL MANUFACTURERS ASSOCIATION, PRESCRIPTION DRUG INDUSTRY FACT BOOK, 1968, p. 29.

t an annual rate of 12 percent during the 1940–966 period—twice the rate of growth for the omestic market, although beginning, of course, rom a much lower base. Foreign drug sales exeeded a billion dollars in 1967 and now account or at least one-fourth of total global sales of U.S. ompanies—in some cases 40 percent or more of a ompany's sales. (*81*, p. 135)

Drug imports in 1967 totaled $75 million, an ncrease of 3.3 percent over 1966. In 1968, they re expected to reach $78 million, reflecting the mpact of Kennedy Round tariff developments on he import picture as a whole. (*81*, p. 136)

Figure 3 indicates the growth of U.S. prescription drug sales in foreign companies, and the declining importance of exports made directly to overseas customers. Intracompany sales to foreign affiliates were excluded to avoid double counting, since these shipments were reflected in the value of sales abroad.

While drug sales of overseas affiliates and subsidiaries of U.S. drug firms rose from $809 million in 1963 to $1.2 billion in 1966, this apparently was not at the expense of exports. The rise in sales abroad permitted intracompany exports of intermediate products to rise from $91.3 to $131.5 million and export sales to other firms to rise from $56.4 to $69.5 million during the same four-year period. (*59*, p. 32)

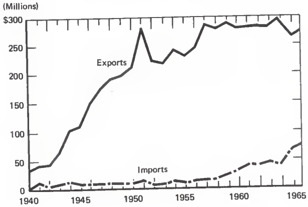
In many countries, notably those in which vigorous home industry competition exists, some prescription drugs manufactured in the U.S. are sold at lower prices than in this country. For example, the price of Meticorten (prednisone) set by Schering Corporation at the wholesale level was reported to be $5.65 for 30 5-mg tablets in the

United States, $3.66 in Italy, $3.68 in Mexico, $1.59 in Brazil, and $1.37 in Switzerland. (*90*, p. 657)

The reasons for these price differences may include less brand-name protection in foreign countries, greater price competition among drugs in various therapeutic classes, different distribution costs, and the requirement for price negotiations set by foreign governmental agencies before they will accept a drug in an official formulary or permit its import and sales.

Figure 4 reflects foreign trade in both prescription and nonprescription drugs and includes intracompany sales to affiliates abroad. Using this measure of economic activity, it can be shown that the value of all pharmaceutical exports climbed dramatically through the 1940's and 1950's. The ratio of exports to imports reached as high as 36 to 1 in 1952, although recent years have brought a decline in the ratio to 4 to 1 in 1966. (*59*, p. 31)

Figure 4.—Foreign Trade in Prescription and Nonprescription Drugs



SOURCE: PHARMACEUTICAL MANUFACTURERS ASSOCIATION: PRESCRIPTION DRUG INDUSTRY FACT BOOK, 1968, p.31.

Because the overseas investments of U.S. drug firms are relatively older and more mature, because they have been able to support these investments with a relatively higher proportion of nonmonetary inputs (i.e., patents, technology) and have been assiduous in borrowing locally to minimize the outflow of dollars, the repatriation rate of dividends, royalties, etc., has been 75 percent higher, relatively, compared to dollar outflow during the period, than for American industry as a whole. (*59*, p. 30)[a]

At least 28 of 40 drug firms active in selling drugs abroad have one or more plants in foreign countries—39 percent in Latin America and 29 percent in Europe. Manufacturers with annual foreign sales of $50 million or more account for nearly half of all U.S. plants and distributorships overseas and a slightly lower percentage of foreign sales offices. Altogether, U.S. pharmaceutical manufacturers have 277 plants, 367 sales offices, and 554 distributors in various parts of the world. (*59*, p. 30)

Sales by Therapeutic Class

Among the hundreds of major and minor prescription drug categories, those in which the change in sales dollar volume was most pronounced between 1955 and 1960 were the diuretics and psychotherapeutic drugs. In the three-year period, 1962–1965, U.S. sales of drugs in these therapeutic classes accounted for 26 percent of the entire market.

Sales of pharmaceutical preparations in other therapeutic classes also increased markedly between 1962 and 1965: parasitic and infective diseases, from $389.7 to $491.6 million; digestive and genito-urinary system, $267.2 to $350.9 million; neoplasms, endocrine system and metabolic diseases, $242.2 to $335 million; respiratory system, $144.6 to $175.3 million; cardiovascular system, $125 to $175.9 million; and skin, $55.4 to $74.6 million. (*59*, p. 12)

The Industry's Dollar

Ever since Senator Estes Kefauver in 1961 asked 22 drug companies to break down their 1958 sales dollars into cost components, there has been controversy over relative values assigned to various company functions.

The National Science Foundation (NSF) gave a figure of 6 percent in 1958 for drug industry research and development (R & D) in the U.S. The pharmaceutical industry contends that 6 percent—even in 1958—was an understatement of the R & D proportion of the sales dollar. The industry says that the estimate was low, since NSF used as denominator the total product sales—including ondrug items—of diversified companies. It did ot list R & D costs of some pharmaceutical divisions of chemical firms, and it did not count foreign-based research.

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[a] Recent studies based on the results of the Corporate Voluntary Program of the U.S. Department of Commerce reveal that 19 U.S. drug companies increased their rate of foreign exchange generation during the period 1964–1966 by 28 percent, while the rate of increase for 722 U.S. firms of all categories participating in the program was 14 percent. The 19 companies generated an estimated $555 million in dividends, royalties, and fees in the 1964–1967 period, with an outflow of only $204 million in direct foreign investment.

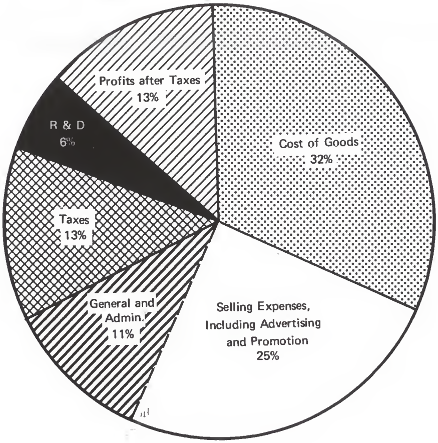
A PMA survey found that, among those of its members that did conduct research—about 80 of the 136 firms—the average manufacturer spent 10.9 percent of his pharmaceutical sales dollar on R & D in 1966. (*60*, p. 13) In 1967, PMA estimated that R & D cost its member companies nine times the amount they spent in 1951.

The industry also says that an average cost of nearly 25 cents of every 1958 sales dollar attributed in the Senate study to "selling" was misleading and should have included such "marketing" expenses as product surveys and planning, warehousing, and company distribution of products to wholesalers and retailers.

Agreement was not reached in 1961 on the "cost of goods sold" because the industry said drug production included quality control and pilot plant expenses as well as normal material and labor costs. Only on taxes and profits after taxes—data readily available from government and financial house records—was there accord between the 22 companies and the Senate Subcommittee. Figure 5 indicates how the Kefauver Subcommittee interpreted the industry sales dollar in 1961, based on 1958 operations of a 22-company sample.

By 1967, the situation had changed somewhat. The drug industry has surveyed itself annually since 1958, through the PMA, to determine averages for the cost of doing business. Some data, however, such as on production costs and quality control, marketing, and general administrative expenses, still are not available on an industrywide basis.

Figure 5.—Breakdown of Drug Industry Sales Dollar, 1958



SOURCE: REPORT ON ADMINISTERED PRICES OF DRUGS, SUBCOMMITTEE ON ANTITRUST
AND MONOPOLY OF SENATE COMMITTEE ON THE JUDICIARY,
S. REP., NO. 448, 87th CONGRESS, 1st SESSION. (1961) REPORT 31, p. 157.

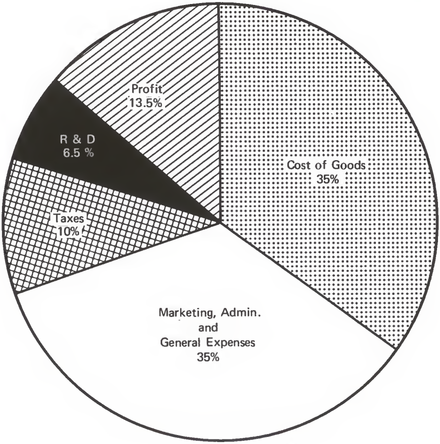
Statistics of the Federal Trade Commission and the Securities and Exchange Commission show that the industry's average sales profit after taxes for the 10-year period ending in 1966 amounted to 10.3 percent. For 1967, the industry's return on sales was reported as 10.1 percent.

On the basis of analyzing published 1966 financial data on 17 of the most successful pharmaceutical companies in the U.S.—but excluding foreign-owned firms—shares of the sales dollar attributed to various operating functions and expenses were estimated by the Task Force with what is believed to be a fair amount of economic realism (Figure 6). The profit percentages shown here are generally higher than those noted in 1961; and the research and development costs generally are lower than are those now estimated by PMA for its members.

R & D expenditures, as a percentage of pharmaceutical sales, are probably higher for companies which produce largely prescription drugs, because more than half of the 17 firms are diversified businesses in which total sales include far more items than prescription drugs and related products.

In Figure 6, percentages of the 1966 sales dollar believed spent for various broad categories of expenditure—including marketing and administrative overhead—are estimates based on financial reports and on testimony by company officials before legislative groups.

Figure 6.—Breakdown of Drug Industry Sales Dollar Among 17 Leading Diversified and Specialty Manufacturers, 1968



SOURCE: MOODY'S INVESTORS SERVICE, INC.; STANDARD & POOR CORP.; MERRILL, LYNCH. PIERCE, FENNER & SMITH, INC.; FDC REPORTS, APRIL 15, 1968.*
* (COMPILATION OF DATA ON "TOP 15" AND "DIVERSIFIED FIRMS:" ABBOTT, BAXTER, LILLY, MALLINCKRODT, MERCK, PARKE-DAVIS, ROBINS, SCHERING, SMITH KLINE & FRENCH, SEARLE, SYNTEX, UPJOHN, BRISTOL-MYERS, CARTER-WALLACE, PFIZER, RICHARDSON-MERRELL, WARNER-LAMBERT.)

CHAPTER 4

RESEARCH AND DEVELOPMENT

A number of new prescription drugs emerge from the pharmaceutical industry's laboratories every year.

Some of these drugs bring better health and longer life to millions of people. Others, such as oral contraceptives, depressants, and stimulants, already have begun to challenge traditional concepts of social behavior.

Billions of tablets, capsules, ampules and other dosage forms of medicinal drugs find their way each year to the druggist's shelf, the hospital pharmacy and the doctor's desk. An unknown but apparently large amount of dangerous drugs is peddled in black markets patronized by those who abuse stimulants, depressants and tranquilizers. Some are spurious imitations of respected brand-name drugs, but most are legitimate products diverted illegally from their destinations throughout the country. The greatest volume of prescription drugs, though, moves legitimately and quickly to patients for whom pharmacists in 1966 filled more than one billion prescriptions.

Results of Research

The effects of drug research and development on prolonging life and on reducing the incidence and duration of illness are well known. Drug research achievements can be observed today in the improved control of cardiovascular disease, diabetes, malaria, streptococcal and staphylococcal infections, meningitis, pneumonia, and even some forms of cancer. Steroid hormones have greatly reduced the pain and crippling effects of arthritis and other inflammatory diseases. Tranquilizers and other psychopharmacological drugs have done much to reduce the hopelessness of mental illness. New vaccines have dramatically reduced the toll of polio, whooping cough, and measles.

In 1969, additional therapeutic drugs are expected to reach patients as the industry continues its search for new products. More than 1,600 chemical compounds developed by the drug industry are currently under clinical investigation. (*81*, p. 136)

Extent of Research

The greater part of the total industrial research and development (R & D) effort in the United States is financed by the Federal government. Since 1957, Federal funds have accounted for substantially more than half of all R & D funds expended each year by all industry. (*51*, p. 20) But in the prescription drug industry, 1966 data indicated that Federal funds financed only about 4 percent of R & D activities. (*59*, p. 38)

In view of the heavy impact of Federal R & D funds in other industries—and especially because the U.S. finances about 65 percent of all public and private health-related research—it seems paradoxical that so little government money is invested in direct drug product research. A recent study reported that:

> ". . . companies with less than ten percent of their R & D funded by federal contracts tended to place prime importance on providing a service to the government. They were not motivated by profits or expansion of their R & D facilities through using federal funds." (*48*)

In 1963, President John F. Kennedy directed that patents for products or processes developed as the result of academic or commercial health-related activities financed with Federal funds must revert to the government. It is understandable, therefore, that drug companies might be reluctant to accept Federal funds for development of new products over which they would have no economic control. While drug-related research and development is undertaken by groups other than industry—educational institutions, nonprofit foundations, and the government itself—drug companies accomplish most of the total R & D related to drugs, and finance this effort almost entirely from their own funds.

Government Share. The limited direct Federal participation in the drug industry's research activities does not mean the Federal government is only a minor force in the overall biomedical research effort. During the past 10 years, there has been a considerable increase in government spending in drug-related research.

In 1968, various Federal agencies are spending more than $100 million on direct and indirect drug-related research. Some of these funds are being used for practical development studies; some are invested in the support of fundamental research. In addition, part of the Federal investment is in the training of pharmacologists, chemists, physicians, and other professionals.

Without the results of such investigations and training, much of the developmental work conducted by governmental and industrial researchers alike would be difficult if not impossible.

The National Institutes of Health (NIH) currently are spending an estimated $51 million per year on intramural drug-related research, spread among nine institutes and two divisions. In addition, in 1967, the NIH supported some 1,000 extramural grants—valued at about $38 million—in the general area of pharmacology. About 480 of these grants—valued at $22 million—were related in some way to the use of drugs in humans.

The National Cancer Institute alone, during the decade 1955–1965, spent one quarter of a billion dollars to develop a framework for research on anticancer drugs that has led to the current highly coordinated, full-scale effort in this field. The National Institute of General Medical Sciences expects to spend about $5.5 million in 1968 to support its pharmacology and toxicology investigations. The National Institute of Mental Health, with 202 grants for pharmacological studies, allotted almost $10 million to this activity in fiscal year 1967.

The largest clinical pharmacology unit in the world—where many of the country's academic clinical pharmacologists are trained—is the Laboratory of Clinical Pharmacology in the National Heart Institute. The Section on Clinical Pharmacology has pioneered in applying basic biochemical and pharmacological knowledge to the solution of clinical problems. Trainees from this laboratory have gone out to establish clinical pharmacology units in universities throughout the Nation. From these academic settings, the prescription drug industry has recruited many of its most productive and distinguished scientists.

The Public Health Service's intramural and extramural program of drug-related studies spent about $3 million in the last three years for various projects conducted by the Centers for Communicable Diseases, Radiological Health, Urban and Industrial Health; its Divisions for Dental Health and Direct Health Services; and universities and PHS hospitals throughout the country.

Pharmacological research by the Food and Drug Administration in 1967 included more than $2.5 million for 15 projects of its Bureau of Medicine. These included studies ranging from adverse reactions from the use of oral contraceptives to the efficacy of drugs marketed between 1938 and 1962.

The Department of Defense will spend about $10 million for pharmacological research on antimalarial drugs in 1968; another $1.5 million is earmarked for work on antiradiation drugs.

Though not strictly research, the Investigational New Drug (IND) and New Drug Applications (NDA) programs of the FDA play a major role in drug development. The FDA is required to pass on the safety of all new drugs and, since 1962, it has been under a Congressional mandate to check prescription drugs for therapeutic effectiveness as well.

The average cost of processing one NDA, including IND proposals and supplements, is estimated at $20,000. In 1967, the drug industry brought to the market 25 new drug entities for which the FDA had approved New Drug Applications.

In addition, a substantial portion of the Federal government's multi-billion dollar biomedical research activities concern projects which may be expected to have an eventual bearing, directly or indirectly, on the development of new drugs. In all these operations—research, product development, and training—the Federal and industry programs, along with those conducted independently by universities and private research institutions, have complemented each other effectively.

Industry Share. The drug industry spends a higher proportion of its own funds for research than does any other industry, and at a rate almost three times that of all industry. (*51*, pp. 68–69) Some individual drug companies expend even larger proportions, while others spend little or nothing.

Total industrial research expenditures on drugs for human and animal use were budgeted at $476 million in 1967, nearly 14.5 percent higher than in 1966; (*60*, p. 3) the figure was only $50 million in 1951. Included in these figures were $13.8 million in 1967 and $14 million in 1966 for company-conducted but government-financed drug research.

During 1965–66, nearly $90 million of the industry's R & D budgets was spent for research on neoplastic and endocrine diseases; more than

$50 million was spent on cardiovascular research; and another $93 million on diseases of the central nervous system.

Over the past decade, industry spokesmen say, the average research and development cost of each important new drug has been $7 million. (*59*, p. 39) Companies with the greatest R & D investments also have the highest sales volumes and are among the most profitable, as indicated in Table 1.

The drug industry employs about 19,000 scientists and other staff in medical and health-related research. Most are supported by about 30 companies with annual sales each of at least $30 million, and these firms are responsible for the lion's share of R & D. They also support, in large part, the extramural research of investigators selected by the Pharmaceutical Manufacturers Association Foundation, Inc., and the research activities of several drug company foundations.

The dollar amounts of R & D reported by drug companies are based on the Internal Revenue Code definition of "research and experimental expenditures," (*85*) and include money spent for extramural research. The National Science Foundation (NSF)—while also including extramural activity in its pharmaceutical research compilations—may, however, exclude the R & D of pharmaceutical divisions in large chemical companies. Use of the NSF definition, may thus lead to under-reporting of actual R & D effort. (*59*, p. 40)

Table 1

Relationship of Research and Development Expenditures, Sales, and Income in the Prescription Drug Industry, 1967[a]

Company	R&D expenditures (in millions)	R&D expenditures as percent of total sales	Net sales (in millions)	Net income after taxes (in millions)	Net income after taxes (percent of equity)
Abbott	$20. 5	6. 7	$303. 3	$28. 1	14. 4
Lilly	40. 7	10. 0	408. 4	53. 7	19. 2
Merck	47. 7	9. 0	528. 1	89. 6	25. 5
Parke, Davis	16. 5	6. 9	239. 0	21. 0	10. 2
Pfizer	23. 9	3. 7	638. 0	57. 5	13. 9
Richardson-Merrell	12. 0	4. 5	100. 9	21. 0	21. 1
Schering	12. 5	8. 3	150. 7	19. 0	20. 0
Smith Kline & French	26. 0	10. 0	260. 0	42. 1	26. 9
Upjohn	30. 2	11. 1	273. 0	31. 4	14. 0

[a] Source: Derived from data reported in FDC Reports, April 15, 1968; Forbes, January 1, 1968; and Fortune, July 1968.

Product Development

The drug industry is reported to channel nearly 16 percent of its total R & D commitment into basic research, compared with an average of 4 percent for all private industry. (*50*)

However, applied research constitutes the bulk of drug industry R & D efforts. The goals of applied research are to translate new knowledge found through basic research into effective pharmaceutical products and to provide efficient ways of manufacturing these products.

New Entities. Between 1940 and 1967, the industry introduced 848 new drug entities—not including biologicals—in 41 separate therapeutic categories.

In pharmaceutical parlance, a new chemical entity is a unique compound unlike any other drug. It may become the active ingredient in one or more drug products, or it may appear as one of two or more active ingredients in so-called combination products.

According to one survey, 525 of the drugs introduced in the 1940–1967 period originated in the United States. Eighty-seven percent—457—originated in the laboratories of American pharmaceutical manufacturers. Non-industry sources produced 68. (*16*)

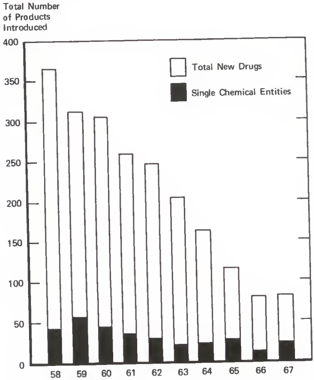
All new single drugs marketed in England, France, Germany, Italy, and the U.S. in 1967 were developed by pharmaceutical manufacturers.

The 25 new drugs approved for sale in the U.S. by the Food and Drug Administration in 1967 were developed by 13 American and four foreign drug makers; 20 originated in the U.S., five in Europe.

Some observers believe a plateau has been reached in the discovery of new drugs, but others say that research has peaks and valleys, and that the industry has just left a valley. Although the rate of industry research and development spending has spiraled upward in recent years, the annual number of new chemical entities has steadily decreased from a peak in 1959, and only started back up in 1967 (Figure 7).

Others see the 1962 amendments to the Food, Drug and Cosmetic Act as a factor in lengthening the time needed for premarketing research and for Federal approval of new drugs. (*15*, p. 3) The amendments—known as the Kefauver-Harris Act—greatly strengthened the powers of the Food and Drug Administration with respect to premarketing testing of drugs, advertising to physi-

Figure 7.—Relationship of Single Chemical Entities to Total New Drugs Introduced in the United States, 1958–1967



SOURCE: PAUL deHAEN, 1967 NEW DRUG PRODUCTS, DRUG AND COSMETIC INDUSTRY, MARCH 1968, p.2.

cians, information on side effects, and other matters.

Many believe the amendments would never have been passed if the thalidomide tragedy had not aroused the public to the need for corrective legislation. Thalidomide is the sleep-inducing drug which may cause deformities in unborn babies, and in Europe was definitely linked to thousands of such occurrences. The drug was not cleared by the FDA in this country although it was widely marketed abroad by its German developers and their foreign licensees.

Nevertheless, millions of tablets of Kevadon—the brand name the product was to be given in the U.S.—were distributed by the American licensee to doctors for clinical testing purposes. In this country, the teratogenic consequences of thalidomide use did not even remotely reach the proportions attained abroad but they were sufficient for swift action by the Congress in October 1962.

In the case of thalidomide, the medical community here and abroad recognized the drug's danger to pregnant women after word of deformities among babies in Europe was carried in the professional literature. But by then so many versions of the drug had been marketed by foreign licensees under different brand names that some physicians were unaware that Kevadon was the same product.

Other Drug Products. The introduction of new chemical entities does not tell the entire story of drug research and development. Between 1950 and 1959, for example, a total of 4,667 new prescription drug products were introduced in this country, of which only 337 were new single entities. The others were combination products and duplicate drugs.

Between 1957 and 1968, as shown in Table 2, the number of new prescription drugs dropped to 2,131, of which 311 were new single entities. Combination products totaled 1,440 in this period and 380 were duplicate drugs. In addition, 656 new dosage forms were marketed.

As Table 2 shows, the introduction of new combination products, new duplicates, and new dosage forms has been slowing during the past decade. For new combination drugs, the high point was

Table 2

Pharmaceutical Specialties Introduced in the United States, 1958–1967 [a] [b]

Year	Number of firms	Total new products [c]	New single chemicals	Duplicate single products	Combination products	New dosage forms [c]
1958	126	370	44	73	253	109
1959	107	315	63	49	203	104
1960	109	306	45	62	199	98
1961	111	260	39	32	189	106
1962	108	250	27	43	180	84
1963	89	199	16	34	149	52
1964	82	157	17	29	111	41
1965	65	112	23	18	71	22
1966	52	80	12	15	53	26
1967	49	82	25	25	32	14
10-year total		2, 131	311	380	1, 440	656

[a] Source: de Haen, Paul: "1967 New Drug Products," Drug and Cosmetic Industry, 102: 43 (March 1968).

[b] Key: *New single chemicals*—products which are new single chemical agents not previously known, including new salts. *Duplicate single products*—products such as reserpine or tetracycline which are produced by various manufacturers. *Combination products*—any product having more than one active ingredient. *New dosage form*—if a product has originally been marketed in tablets and is now offered in capsules, suppositories, etc.

[c] New dosage forms are not included in total new products.

253 in 1958; by 1967, the number was only 32. In 1961, 106 new drug dosage forms were introduced; in 1967, the number was only 14. Even duplicate product introduction varied considerably after 1962. (*15*, p. 4)

The trend toward steeper research costs and less productivity over the years may have resulted from several technical factors. One observer believes that future research problems may be more difficult:

"The attack of the scientific community on disease has been like clearing a field of small rocks until only the big boulders remain," he said. "These will take a great deal of work and time. Advances in drug therapy have taught us that we must move much more cautiously, since changing one body function may affect others adversely. Progress has been made in the alleviation of disease but we are now looking for total cures. This is much more difficult to achieve, and in some areas may even prove impossible." (*15*)

Many in the drug industry, however, cite greater difficulty in obtaining approval of new drug applications, higher costs of professional research manpower, and competition among new products as factors most responsible for the recent trend toward development of drugs with genuine and demonstrable improvements over existing medications. (*61*)

Research Directions

The extensive research program of the drug industry is generally described as aimed at better health and finding safer and more effective chemical or biological agents for the prevention and treatment of disease.

Most of the firms in the industry are stockholder-owned and are profit-oriented. The goals of therapeutic progress and financial success, however, need not conflict; in fact, the way to the greatest financial success is through significant breakthroughs in drug therapy.

The industry's R & D effort also may be described as aiming at higher profits by companies obtaining patents which help to protect shares of the prescription market in one or more therapeutic categories. Although it is true that a patent cannot assure commercial success, it is evident in the case of new drugs that success cannot be readily attained without patent protection.

Industry-created obsolescence of prescription drug products is apparently considered to be a major research goal, as was pointed out by a marketing research expert:

> "There are no longer panaceas which are good for all the ills of man or beast. Rather, we offer more and more specific medications and each product compares, or will compare, with a limited number of other products in its own area. The typical company is active in only a limited number of these market segments . . . Because each company tends to concentrate its research in areas where it has the most experience and the most competence, we often seem dedicated to outdating our own best products." (*31*)

As one company executive put it: "No industry in the country or indeed in the world spends a greater percentage of its sales dollars for the elemental objective of making obsolete the products from which these dollars are realized." (*73*)

Company Concentration. A listing of reported research and development expenditures by nine drug companies (Table 1) indicates a high degree of correlation among firms with strong R & D assets, high sales volumes, and favorable rates of return on investment.

In 1967, some 19 pharmaceutical firms accounted for more than $341 million of drug research and development, not all in prescription products. (*17*, p. 10) These companies also were among the highest earners in 1967.

One of the more difficult and more controversial considerations is the relationship between research and profitability. The research-conscious drug industry is highly profitable; within the prescription drug industry, the firms that account for most of the research earn most of the profits and have a high rate of profitability. But the relationship between the two is uncertain. Although certain correlations exist, it is not precisely clear at this point whether extensive R & D is the *cause* of high profits, or the *result* of high profits; or if both extensive R & D and high profits are the results of other factors.

Product Concentration. New drug products from different companies constantly move into the strongest sales positions, causing a decline in the market share of older drugs and changes in the sales ranking of the drug makers. In fact, 68.6 percent of all prescription drug products sold in 1951 were no longer available in 1960, having been replaced by newer and more popular medicinals.

Drug obsolescence caused by new product introduction continues to the present.

Among the 823 new single drug entities introduced in the past 26 years, anti-infectives accounted for 18.3 percent. Cardiovascular preparations ranked second (8 percent), followed by tranquilizers (4.4 percent); antihistamines (4 percent); skin preparations and diuretics (each 3.8 percent); analgesics (2.8 percent); cough and cold preparations (2.7 percent); anesthetics (2.4 percent); cancer chemotherapeutic agents (2.2 percent); and antiobesity and eye preparations (each 1.8 percent). Other therapeutic classes accounted for smaller shares of the total. (*14*)

Among the prescription drugs most heavily prescribed today are the antihistamines, cardiovascular preparations, anti-infectives, cough and cold preparations, diuretics, hormones, tranquilizers, gastrointestinal preparations, muscle relaxants, sedatives and hypnotics. Of the 10 industry sales leaders in 1967, each had at least one new drug entity represented in half or more of these therapeutic classes.

Table 3 indicates the number of new single drugs in the major therapeutic classes which were introduced between 1940 and 1966 by companies considered to be today's sales leaders. In addition, each of these companies also produced other drugs which (1) closely duplicated the products of one of their rivals; (2) were combinations of another drug and a product made by themselves or a rival; or (3) were new dosage forms of their own or the original products of others.

Drug Proliferation

The total of pharmaceutical products available to practicing physicians in the United States has grown to enormous size, although the exact number is unknown even to industry associations and Federal agencies. The manufacturers that produce 95 percent of the Nation's prescription drug products estimate there are about 4,000 different dosage forms of 1,200 single drug entities, and about 6,000 combinations, a total of 10,000 products in a variety of package sizes. (*61*) In other countries, such as Germany and France, the figure may be higher. (*83*)

Proliferation of prescription drugs in the past two decades has led some economists and physicians to criticize the direction in which they believe the industry's research and development efforts appear to be leading.

One economist alleges that much of today's drug research is imitative or is directed only toward novelty and patentability. (*65*) In medical circles, some doctors contend that the great profit potential tempts a few manufacturers to put new drug products on the market which do not represent significant advances in therapy. It is maintained that the industry is characterized by much so-called molecular manipulation, leading to the development of "me-too" drugs—substances which are not significantly different from other drugs, nor significantly better—but which are sufficiently manipulated in chemical structure to win a patent. (*29*, *76*) Similarly, they maintain that the

Table 3

1967 Drug Industry Sales Leaders and Number of New Drugs Developed 1940–1966, by Therapeutic Class (10 Companies) [a] [b]

Therapeutic Class	Merck	American Home Products	Lilly	Abbott	Pfizer	Bristol Myers	Smith Kline & French	Upjohn	Richardson-Merrell	Parke, Davis
Antihistamines	1	2	2	1	1	3	--------	1	1	2
Anti-Infectives	12	8	15	8	9	9	2	9	3	10
Tranquilizers	2	5	1	------	2	--------	5	--------	2	-----
Cardiovascular Preparations	4	2	4	3	1	1	1	--------	2	2
Cough and Cold Preparations	1	1	4	------	3	--------	2	--------	1	-----
Diuretics	3	2	3	1	1	1	2	1	--------	-----
Gastrointestinal Preparations	3	6	2	1	1	1	1	2	1	1
Hormones	8	2	2	1	3	1	--------	10	1	3
Muscle Relaxants	1	--------	2	------	------	--------	--------	--------	--------	-----
Sedatives and Hypnotics	2	1	2	2	------	1	--------	--------	--------	-----
Totals	37	29	37	17	21	17	13	23	11	18

[a] Source: de Haen, Paul: "Compilation of New Drugs," American Professional Pharmacist 33:25–62 (Nov. 1967).

[b] "New Drugs"—single chemical or biological entities

ndustry devotes much effort to the development of combination products—products containing two or more well-known substances in a new combination—which contribute little or nothing to improved therapy. (*37*)

It is obvious that the industry does devote effort to the development of such products, but the relative amount cannot be determined with accuracy. Since important new chemical entities represent only a portion—perhaps 10 to 25 percent—of all new products introduced each year, and the remainder consists merely of minor modifications, new dosage forms, or combination products, then much of the industry's research and development activities would appear to represent only minor contributions to medical progress.

The development and introduction of duplicative or combination products cannot be considered as an inexpensive fringe benefit. Each requires more or less costly laboratory research, clinical tests, and the preparation of sufficient evidence to demonstrate to the Food and Drug Administration that the new product is at least safe and effective.

The fact that in fiscal year 1967 the FDA found 425 New Drug Applications (of all types) "incomplete or not approvable," and approved only 83 NDA's indicates that, even with more stringent government regulations, the drug industry either (1) has yet to place major emphasis on development of demonstrably different, more effective products, or (2) has been generally unable to supply the kind of hard evidence which the FDA now requires before an NDA is approved.

To the extent that an industry devotes a considerable share of its research program to the development of what have been termed duplicative and noncontributory products, there may be a waste of skilled research manpower and research facilities, a waste of clinical facilities needed to test the products, a further confusing proliferation of drug products promoted to physicians, and a further burden on the patient-consumer who, in the long run, must pay the costs.

Industry spokesmen have contended that although there may be very small differences among these products, even these might be of great therapeutic value—at least to some patients—and that the development and promotion of company specialties is important in adding to the physician's armamentarium. (*61*) Whether such additions make the armamentarium better or merely bigger has not been objectively determined.

Industry spokesmen also contend that even new dosage forms of the same drug may result in substantial savings in total treatment cost. If, for example, a patient can be maintained in a stable condition with a medication that reduces the required number of visits to his physician, then the total cost of his medical care will be reduced for that episode of illness. (*61*)

Reference in 1961 Senate hearings to "molecular modification" of existing drugs, (*34*, pp. 36–37) in order to obtain patent protection, has led to much scientific and philosophical discussion. In 1963, at a Johns Hopkins University conference on drugs, a physician and pharmacologist said:

> ". . . In my opinion, the time has come for those responsible for the introduction of new drugs to reflect seriously on how they invest their share of the Nation's limited supply of money, effort, time, and scientific manpower. I have a strong suspicion that most administrative and scientific officers of pharmaceutical companies know whether a new drug they are considering or promoting is one that is trivial, second or third order in importance, a potboiler, or a minor molecular modification of little consequence. I am not saying that one of these agents may not eventually prove to be an important contribution or even a major breakthrough, but the chances are very, very slim, the cost is quite considerable, and the therapeutic jungle is thick enough without it. There are good and bad reasons for introducing a new drug; only the socially and scientifically acceptable good reasons should determine policy . . ." (*29*)

Commenting on trends in drug research, the New York Academy of Medicine's Committee on Public Health noted in 1962:

> "Now the stage is set and the performers were ready for growth, expansion and extension. All this came with such a surge that new products appeared in what may fairly be called flood proportions . . . It has been estimated that of the 400 new products introduced by pharmaceutical companies each year, not more than 40 are new entities . . . the remainder are congeners—i.e., slight modifications of existing products. But it should be remembered that slight changes in a chemical compound alter its therapeutic properties, and most chemical compounds are capable of being modified in almost innumerable ways. Probably the actual new drugs that

> represent improvement in therapy are fewer than six a year." (*53*)

The research director of a leading prescription drug company said in 1964:

> "We cannot ignore the criticism that we have created an abundance of new drugs related structurally and therapeutically, which in the opinion of many serious-minded clinicians contribute little but confusion . . .
>
> "In viewing the congener-drug developments of recent years, I have often wondered why medicinal chemists in so many laboratories had chosen to direct their efforts into molecular modification of new drugs discovered by others. Although this massive surge has created new knowledge for the medicinal chemists at an almost explosive rate, its productiveness in the field of medicine can be questioned." (*76*)

A university economist, who has testified before the Senate on behalf of the prescription drug industry, said in 1963:

> "Significantly, research and development expenditures for the industry frequently amount to as much as two-thirds of the profits of the preceding year after taxes, suggesting that profitability and inventive effort go hand in hand. The social costs of this apparently intensive search for new drugs as reflected by their relatively high (high relative to production costs) and inflexible prices during the first few years of commercial use probably fall considerably short of their social benefits.
>
> "It is not at all clear, however, that the same economic conclusion applies to the maintenance of inflexible prices on individual drugs after new, substitute drugs have substantially reduced sales of the former, or to the introduction of new brand names purely for the purpose of avoiding price cutting on existing drugs.
>
> "In any industry, however dynamic or creative, left to regulation by the private market's forces of supply and demand, price competition still plays a vital allocative role. When duplicative product development is substituted for such conventional price competition, it may adversely affect the public in two ways: it may shift some of the scarce professional research talent from new to duplicative drugs where their marginal productivity is lower, and it may deprive the public of lower prices in drugs that are highly effective in the treatment of certain diseases, even though new and more effective drugs have begun to invade these markets." (*41*)

CHAPTER 5

PRODUCTION AND QUALITY CONTROL

Production and quality control are difficult to separate because of the ways in which they interact. Production starts with the selection and testing of drug ingredients, and continues until the finished product is ready for shipment to the wholesaler, community pharmacist, or institution.

Quality control is—or should be—part of each step in that process, consisting of "all planning, testing, and supervision which guarantees the consistent production and proper distribution of a drug product with the purity, potency, uniformity, and physical characteristics best suited to obtain a favorable therapeutic response for the consumer." (*59*, p. 25)

Utilizing a number of techniques, some major brand-name companies have placed heavy emphasis on their own quality control programs, and implied more or less directly that some other companies—notably those which produce low-cost chemically equivalent drugs—have less than adequate quality control.

For example, one major company recently advised physicians as follows:

> "Low cost, unbranded drugs may be manufactured by firms that lack the experience, formulation know-how, constant and costly quality control, and special equipment employed by manufacturers who proudly brandname their medicines." (*9*)

It is true that some low-cost, generic-name drugs may be manufactured under such unsuitable conditions. It is also true that some high-cost brand-name drugs may also be produced in such fashion. ditions. It is also true that some high-cost, brand-name drugs are made under appropriate quality control—and so are some low-cost, generic-name products.

Evidence based on the rate of drug recalls—for subpotency, mislabeling, contamination, and other defects—indicates that quality control is not invariably adequate, regardless of the presence or absence of a brand name.

Production

If quality production is the sum of the manufacturer's knowledge and skill in producing safe and efficacious drugs, certain production techniques are his economic bread-and-butter.

A drug company which obtains a patent on a new drug process or product is gambling millions that its marketing activities and reputation as an innovator will enable it to recoup research and development costs in a relatively short time. It is aware that other drug companies may be working on variations of the same drug which eventually may become its competitors in the marketplace. Therefore, the security of its production processes—proportions of ingredients, length of mixing time, precise temperatures used at various stages, etc.—are of utmost importance. Aside from the uniqueness of a new chemical entity which its R&D may have produced, a drug company's production techniques—or "know-how"—for a particular product are probably its most valuable possession.[a]

Production Economies. In any effort to control the costs of prescription drugs, few large-scale savings can be foreseen as the result of developing improved production methods. There have been exceptions in the past—for example, new processes brought substantial cost savings in the production of the antibiotics and the synthetic corticosteroid hormones—but these have been rare.

In general, neither the cost of raw materials nor the actual expenses of production represent a significant part of the final product cost.

The raw materials are used only in small quantities—most drugs are made in "batches" rather than in continuous-flow processes—and bulk purchases and bulk production methods have little importance in most drug manufacture. According to one company president, there is little relationship between the cost of prescription drug ingredients and the wholesale cost of the product. (*12*) Far more important, he said, are the intricacies of quality control.

Quality Control

An estimated 7,000 workers—or 17 percent of the drug industry's manufacturing staff—are employed in quality control duties. The industry reportedly spends $74 million annually on this function, about 2.4 percent of its domestic sales receipts. (*59*, p. 25)

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[a] For additional comment, see Patents, Trademarks, and Competition, pp. 37–41.

(Twenty-one large firms—many of them U.S. subsidiaries—reported to the Canadian government that quality control expenditures accounted for only 1.2 percent of total sales, or approximately 3.6 percent of the cost of goods sold. (*6*) Industry sources in the U.S. say this is because many of the subsidiaries buy their bulk drugs in powder form which already has undergone extensive testing for quality and purity. Therefore, the Canadian firms have fewer quality control procedures to perform. (*61*))

Maximum control of quality in the production process is essential because the capsule or tablet of medicine the patient swallows has never, in itself, been tested. The patient, therefore, is vitally concerned that the one capsule he is about to take—one of perhaps a million or five million in a pariicular production lot—is as fully potent, effective and free of contamination as the 10, 20, or 100 capsules which successfully passed the required tests. (*13*, p. 992) Only the reputable, professionally and technically proficient manufacturer—large or small—can provide adequate assurance that one lot of therapeutic drug products is as safe and effective as another of the same composition and dosage form.

The Food and Drug Administration is concerned with the composition, safety, and efficacy of prescription drugs and biologicals. Its sample testing and its inspection of manufacturing plants cannot, however, substitute completely for the integrity and step-by-step process and product checking of the drug maker. The purposes of the complex FDA regulations are, first, to supplement the quality control of individual firms, and second, to prevent the marketing of dangerous or ineffective drugs. Samples of drug products which violate food and drug laws may be confiscated and destroyed and production halted, legal proceedings may be instituted, and civil and criminal penalties may be imposed. None of these deterrents, though, is as effective as a threat to the professional reputation of the manufacturer.

Recalls of drugs from the market, for reasons ranging from contamination and subpotency to insufficient labeling and label mixups, occur not infrequently among the products of large as well as small manufacturers. When this occurs, economic loss on the product is likely to be considerable and the reputation of the company may suffer severe damage.

In 1967, for example, 332 lots of drugs were recalled because the products were misbranded, substandard, contaminated, or otherwise in violation of food and drug laws. These involved both large and small manufacturers, and both brand-name and generic-name products. (*87*)

Because the results of careless production methods and insufficient quality control can be disastrous both for the patient and for the drug maker, many manufacturers have erected an elaborate and complicated system of in-plant checks.

One U.S. company calculated that almost 700 quality control checks were involved in the production of a steroid drug product. Another said the production of an antibiotic required 200 checks that took four weeks to complete. A manufacturer who produced both generic- and brand-name drugs testified that making 5 million 100 mg. capsules of a powerful barbiturate required a total of 808 different kinds of quality control checks involving thousands of hand and machine operations. (*13*, p. 984)

Drug makers emphasize that two types of quality control exist: one, testing quality of the product at the end of the procedure; the other, building quality into the entire production, packaging, and distributing system. Manufacturers who build their reputations on consistent safety and efficacy of their products insist that only the second understanding of quality control makes sense. (*13*, p. 985)

Both large and small brand-name and generic-name drug makers who subscribe to effective quality control concepts and practices deplore the actions of companies which do not. The president of one major company, in fact, recently proposed that Federal legislation should be enacted to require all drug producers to meet minimum quality control standards. (*47*)

The FDA has established regulations on Good Manufacturing Practices (GMP) which all manufacturers are required to follow and which, in fact, were based in part on a code developed by the PMA. The Department of Defense and the Veterans Administration have separate quality control requirements for manufacturers who bid on drug orders.

CHAPTER 6

MARKETING

Perhaps no other aspect of the drug industry has been so strenuously criticized as its marketing activities.

Industry spokesmen have claimed that marketing is an accepted part of any business activity; that its marketing costs are reasonable; and that its marketing efforts—including advertising, direct mailings, and personal visits by detail men to physicians—are primarily educational in nature, aiding the physicians and thus benefiting their patients.

On the other hand, critics have asserted that intensive promotional efforts may be acceptable to sell such products as detergents, beer and used automobiles, but not for such necessities as drugs; that the expenses for drug marketing are excessive and add needlessly to the cost of prescriptions; and that much drug promotion—at least until the recent past—has been inaccurate, unscientific and biased.

To industry spokesmen, the promotional aspects of drug marketing are a mark of the intense competition within the industry. Companies defend their promotional activities as part of efficient marketing—what they see as a fundamental mechanism in the U.S. economy—as well as fulfilling part of the total educational function.

In turn, critics insist that such promotional activities are related to the particular type of competition which unquestionably exists in the drug industry—an intense competition between companies, with the promise of a greater share of a relatively limited market and richer profits for the successful competitor—but these activities have little or nothing to do with normal competition in the retail marketplace, with the promise of eventual savings to the consumer. The industry points out, however, that conflicting demands for change occurring both in the public and private health care sectors can only exacerbate the strained positions of companies trying to satisfy the public as well as their stockholders.

The Strategy of Names

Intimately related to the entire subject of drug marketing is the matter of generic and brand names.

PMA spokesmen have stated:

> ". . . The system of using trademarks or brand names is the best known and most effective means of providing responsible identification of finished products, thereby giving the greatest assurance of reliability and predictability in drug therapy." (*55*, p. 1)

The Chairman of the Department of Pharmacology at Creighton University Medical School, however, said:

> "In all that I have read and heard on the subject, I have seen no proof that generic drugs are inferior to trade name drugs . . . I do not believe that there is any justification for the high trade name prices charged the patient, except for higher profits and bigger advertising. The arguments for higher production costs, greater purity and research and development are at best unconvincing and at worst false." (*39*).

Such extremes of opinion require a careful examination of drug nomenclature, and the methods for selecting names for new drugs.

Most generic names are proposed by the research or medical workers involved in the creation and study of possible therapeutic applications of the drug. The name is submitted to the United States Adopted Names (USAN) Council, a coordinating group composed of representatives from the American Medical Association, the *U.S. Pharmacopeia*, the American Pharmaceutical Association, as publisher of the *National Formulary*, and the Food and Drug Administration.

If there is any conflict with existing names, or disagreement as to meaning suggested by a proposed name, further negotiation takes place with the initial sponsor. When agreement is reached, the name is transmitted to the World Health Organization, which works with the official pharmacopeial organizations of many nations.

The Food and Drug Administration has not so far found it necessary to exercise its veto power over final name selection, in part because it participates in USAN Council deliberations. As a final step, the Secretary of Health, Education, and Welfare has the right to designate official names for drugs when he so desires. On the advice of USAN, the Secretary has accepted about 85 Adopted Names since 1962.

The Adopted Names program is now in its seventh year. To date, some 700 nonproprietary names have been assigned and made public. The *Fifth Cumulative List (1961–1966) of U.S. Adopted Names* appeared in booklet form in 1967. The 1967 edition, which superseded four earlier lists, is scheduled to be the last fully cumulative list until the appearance of the tenth annual compilation, which will be cumulative through 1971.[a] Under the present USAN plan, the next four annual editions covering the years 1967 through 1970 will consist of supplements, giving only the new entries, cumulatively, for those four editions as well as any relevant changes affecting previous entries.

Sometimes it is difficult to arrive at a mutually satisfactory generic name. Manufacturers may insist upon names of their own coinage, which may have already appeared in laboratory or clinical reports, labeling, brochures and various marketing media. In 1965, Dr. Joseph B. Jerome, Assistant Secretary of the Council of Drugs of the American Medical Association, emphasized that the primary users of established or generic names are the physicians, pharmacists, and associated professions. At one time, the chemical training obtained by most physicians usually provided an adequate basis for recognizing the relationship between early established names and the actual compounds. With increasing numbers of more complex drugs, however, chemical names and established names derived from them were found to be difficult to spell, pronounce, and remember. Therefore, he said, established or generic names should be coined to be most useful to the members of these professions. The basic requirements are relatively few, he said:

> "These names must not conflict with any established trademarks or nonproprietary names.
>
> "They must be informative; that is, indicate in some manner the general group of drugs to which the compound belongs.
>
> "They must be relatively simple." (*33*)

The last item became an issue in Senate hearings conducted by Senators Russell Long and Gaylord Nelson. At one point in the Subcommittee hearings on Competitive Problems in the Drug Industry, Senator Nelson questioned Dr. James Goddard, the Food and Drug Administration Commissioner:

> "You did not happen to bring along a list of generic names supplied by the brand name companies that are shorter than the brand names they created for themselves, did you?"

To which Dr. Goddard replied: "That would be a very short list, Senator." (*26*, p. 754)

Senator Long also questioned the tactics of prescription drug manufacturers who sell their products by both generic and brand names. While speaking on behalf of a drug formulary amendment to the Social Security Act Amendments of 1967, he said:

> 'There is one thing that these drug manufacturers have in common. They have always tried to see that the generic name, the real name of the product, is some unpronounceable, mouth-filling word, sometimes more than filling one's mouth when it gets tangled up with his wisdom tooth.
>
> "These companies arrange it so that the generic name is not so easy to pronounce or describe and it therefore makes it very easy to get doctors to use short, catchy brand names and to charge ten times as much as they could charge for the same drug by the awkward generic name." (*38*)

Whether or not the manufacturers are responsible, or whether the characteristics of generic names represent conformity to legal requirements, it is a fact that generic names generally, although not always, are more cumbersome than brand names. However, the USAN Council is striving to replace many of these names with simpler versions and to encourage adoption of less awkard terms for new drug products.

Senator Long and others contend that advertising and promotional emphasis on brand names obscures the existence of similar, lower priced drugs that are not trademarked. Drug makers, on the other hand, maintain that many firms—large and small—produce both trademarked and nontrademarked items, and that marketing emphasis on the brand names is necessary as a means of manufacturer identification and to establish confidence in the reliability of the product source.

It appears, however, that marketing emphasis on trademarked names may play a significant role in enabling manufacturers to recover their investments.

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[a] See new cumulative list from June 15, 1961 through December 31, 1967, published in the *Journal of the American Medical Association*, February 26, 1968.

The Makeup of Marketing

Although the details may vary greatly, marketing is usually considered to encompass one or more of the following: *(61)*

Physical Distribution. Included here are such activities as order filling and shipping, warehouse operations, transportation, inventory control, checking trade and hospital inventories, writing orders, authorizing or rejecting returns, and similar operations customarily involved in the distribution of many other commodities.

Industry marketing experts point out that making prescription drug products nationally available is an expensive business. One of the largest full-time manufacturers claims its line of products is always available to 99 percent of the population. Regional differences in drug preferences of prescribing physicians also are said to increase marketing costs.

Market Research, Development and Planning. This aspect incorporates research and development for short-term and long-term planning; development of new products, forms, dosages, strengths, and packages; analysis of market data; and preparation of technical information for public relations, financial reports, and meetings.

As one innovation, some manufacturers are producing tablets and capsules in prepackaged, prelabeled containers holding the number of units most frequently prescribed by physicians, thus saving the time normally required by pharmacists in counting and labeling. This technique—widely applied in Sweden *(83)*—is already being used in the United States with oral contraceptives, and is under consideration for other products.

Marketing Administration. Included are administrative activities related to sales, advertising, and promotion.

Detail Men. These individuals, often specially trained, are used to inform physicians on the availability and appropriate utilization of the company's products. These are considered educational as well as commercial efforts by the companies which employ product representatives.

Advertising and Promotion. This aspect incorporates professional and trade journal advertising, direct mailings, printed promotional aids, merchandising displays and promotional materials for retail and professional use, drug samples, medical information services for physicians, public relations, and (for nonprescription drugs) television, radio, and newspaper and popular magazine advertising.

Included in the promotional activities of some major prescription drug companies have been the support of scientific or medical conferences or symposia; the publication of educational materials for the public on such subjects as immunization campaigns, narcotics and drug abuse, and school health; the support of scholarships and fellowships; and the support of scientific or medical societies.

Also included have been "hospitality suites" maintained for visiting physicians and newspapermen at medical conventions, and gifts to medical students, interns, and residents.

The Costs of Marketing

Among the major brand-name manufacturers, marketing expenses as a proportion of the wholesale sales dollar are difficult to determine.

More than a decade ago, a survey of 23 prescription drug companies listed 15 categories of marketing expenses, totaling an average of 20.6 percent of sales. *(68)*

Spokesmen for some companies claim marketing accounts for no more than 14 to 18 cents of the sales dollar, while others acknowledge that a much higher proportion is spent promoting, advertising, selling, and distributing their products.

In 1961, for example, Schering said that for every dollar of sales, it spent 32.5 cents for promotion and advertising. (*34*, p. 17) Carter's marketing costs were reported to be about 28 cents of every sales dollar. (*34*, p. 32)

Eli Lilly broke out marketing as a separate category in its annual report for 1967, with the expenses in this category accounting for about 18 percent of net sales. Smith Kline & French estimated its 1967 promotional expenditures as about 14 percent of net sales, but SK&F carefully distinguished between its salesmen's marketing and nonmarketing activities. *(92)*

"The fact remains," as one advertising executive put it in 1963, "that, in absolute terms, approximately three-quarter of a billion dollars is spent every year by some sixty drug companies in order to reach, persuade, cajole, pamper, outwit, and sell one of America's smallest markets—the 180,000 physicians . . ." *(25)*

The drug industry's approximately 15,000 detail men cost manufacturers $7.69 per visit to doctors and pharmacists a few years ago. The average cost per reader of a medical journal drug advertisement was about one cent, and the cost per reader of company literature sent by mail was about 17 cents. The precision of these figures may be questionable, but the relative cost of the several types of promotion is roughly as indicated. (*3*, p. 60)

In 1963, *Advertising Age* said that "producers of ethical drugs spend more than $225 million a year on advertising, primarily in medical evaluations and direct mail campaigns.

"Since there are some 200,000 physicians in the country, this works out to an expenditure of more than $1,000 per year per doctor." (*1*)

In 1966, Dr. James Goddard, former Commissioner of the Food and Drug Administration, estimated that $3,000 per physician per year would be a more accurate estimate of the amount spent by drug companies to advertise and promote their products to the Nation's physicians. (*28*) In 1968, he suggested a more accurate figure would be $4,500. (*28*)

In 1967, 42.8 percent ($13.6 million) of the American Medical Association's revenue of $31.7 million was derived from all advertising, including pharmaceutical ads placed in its various publications. (*2a*) The AMA *Journal*, in 1963, carried nearly 6,000 advertising pages a year, a volume exceeded by only one other weekly periodical in the country, *Oil and Gas Journal*. (*1*)

The cost to drug manufacturers for *JAMA* advertisements alone in 1949 was $2.4 million; by 1960 it had risen to $8 million. In addition, the manufacturers in 1960 were said to have paid $900,000 in fees for the use of up-to-date AMA physician lists obtained by eight organizations in the direct mail business. The AMA counsel in 1961 said a royalty of $2 a thousand was paid to the medical association by these organizations. (*34*, p. 76)

It is noteworthy that prescription drug advertising to physicians seldom, if ever, mentions price.

Although published data are not available, it appears that the marketing costs for manufacturers of low-cost generic drugs are minimal, and consist mainly of distribution and direct mail advertising expenses. Few such companies engage in substantial medical journal advertising or promotional activities, primarily because product promotion of generically-labelled products is illogical. Advertising such a generic name as meprobamate, for example, may popularize the use of the product. But since generically-written prescriptions can be filled with *any* brand of the product, the small market shares of firms selling under generic name means that benefits resulting from their own promotional outlays would probably be uneconomic.

The small firms might elect to use their own trade or brand names, and promote them as the large firms do, but their limited financial resources usually make this impossible. Consequently, most such firms are permanently relegated to the use of generic designations for their products.

Effects of Marketing

The portion of the drug company's sales dollar spent on marketing includes more than personal promotion and media advertising, but these two activities probably impinge most directly on the physician's prescribing habits.

Advertising. The prime effect of drug advertising has not been carefully studied. (*3*, p. 56). Nonetheless, some scientists and physicians have been disturbed by drug advertising content and volume, and have voiced strong complaints.

First, there is the charge that sheer volume of drug advertising bombards and overwhelms the physician, capturing his prescribing practices by mass and weight alone. It is estimated that the average medical practitioner receives some 4,000 direct mail promotional pieces a year. One observer points out that "it would take two railroad mail cars, 110 large mail trucks and 800 postmen to deliver the daily load of drug circulars and samples to doctors if mailed to one single city." (*34*, p. 48).

A former medical director of a well-known drug company speaks of the "triphammer effect of weekly mails, the regular visits of the detail man, the two-page spreads, and the ads which appear six times in the same journal, not to mention the added inducement of the free cocktail party and golf outing complete with three golf balls stamped with the name of the doctor and the company in contrasting colors." (*34*. p. 50)

The drug companies, on the other hand, say that more advertising is necessary in the pharmaceutical industry because of the technical nature of their products and the necessity to give complete information on contraindications, warnings of possible side effects, etc. (*61*)

Second, it has been asserted that drug advertising is too "slick" and would be more suitable for less vital products than health-giving drugs. Manufacturers have been charged with being too sanguine in their advertising, greatly exaggerating the benefits of new products and minimizing known defects, or overlooking the fact that little is known about all of the drug's effects. (*52*)

In 1967, the Food and Drug Administration moved to counter this complaint by issuing tentative guidelines on the content and format of prescription drug advertising. The FDA said:

> "To deal with advertisements exaggerating usefulness and playing down side effects and contraindications, we are considering a very comprehensive list of advertising practices which we consider as false, lacking in fair balance, or otherwise misleading." (*86*)

The Commissioner of FDA told the annual meeting of the Pharmaceutical Manufacturers Association in 1966:

> ". . . I would submit that the central dynamic [theme] of the drug industry has been—and must continue to be—the maintenance of the health of all Americans through better pharmaceutical products . . .
>
> "Some advertising cases have been quite abusive of regulations. They have trumpeted results of favorable research; they have puffed up what was insignificant clinical evidence; they have substituted emotional appeals for scientific ones." (*27*)

The drug industry replied that since 1962, at least, product advertising has conformed not only to increasingly strict FDA regulations but also to the ethical standards of the industry's own code. The industry says the advertising control regulations of the FDA have required companies to increase both the quantity and size of product messages in professional journals, forcing some of the publications to change their formats. (*61*)

Detail Men. The medical service representative, or detail man, visits practicing and teaching physicians but rarely "sells" to them in the sense of soliciting and accepting orders for his company's products. He helps physicians in their prescribing practices by providing them with new and useful information about the company products he promotes, and he often educates them in the sense of reporting on the uses of the product in various clinical settings. (*3*, p. 59)

Doctors in the medical departments of the pharmaceutical houses give intensive courses to detail men on the diseases or syndromes that specific drugs are supposed to affect and on the particular uses, advantages and, when requested, the defects of those drugs.

In the last four years a large pharmaceutical company has used programmed instruction courses to provide this intensive training. In addition to in-house instruction, detail men also learn on the job from some of the doctors they inform. What they learn from one doctor, they may also communicate to other physicians and probably also to each other.

Detail men have a variety of functions: to carry information from their parent companies to doctors; to report information from doctors back to their companies; to transmit knowledge and experience from doctor to doctor; to provide companionship and support for some doctors; and, finally, to spread nondrug but professionally important information within the community of doctors.

During the Johns Hopkins University Conference on Drugs in 1963, however, the role of the detail man in persuading doctors to prescribe brand-name drugs came under fire. Because of the company man's representations, it was claimed, many physicians have associated only certain brand-name drugs with quality and therefore favored these brands over others. Yet chemical equivalents of the same drug with equal quality but at lower prices were frequently available. (*74*, p. 294)

An industry association spokesman said, on the other hand:

> ". . . The function of these representatives is more comparable to that of sales engineers or customer service representatives in capital goods industries than to the role of the typical consumer goods salesman." (*61*)

Two surveys showed that (1) the detail man is the most important source of first information received by doctors on new drug products; (*4*, *19*) and (2) that only four percent of the physicians surveyed reported that they refuse to receive detail men. (*91*)

But a teaching physician had this to say:

> ". . . Detail men are valuable for the purpose of getting information to physicians and pharmacists regarding the availability and prices of products distributed by their companies but, being salesmen, they cannot be expected to give unprejudiced advice." (*34*, p. 65)

Drug Samples. The value of drug samples used as promotional materials is currently undergoing serious reappraisal by many prescription drug manufacturers, and some have altered their promotional use.

No accurate estimates exist of the number and dollar value of such samples distributed each year to American physicians and hospitals by manufacturers. (According to the Canadian Pharmaceutical Manufacturers Association, samples distributed to Canadian physicians and hospitals accounted for 3.7 cents of each sales dollar. (7)

In the past, drug samples were distributed—without request—to allow the physician to try a product and discover its advantages on his own patients. With the tremendous number and variety of products now available, however, it appears to be increasingly difficult to induce a physician to undertake such a trial. Furthermore, if he does try a drug, in most instances he can do so only with a very few patients—perhaps half a dozen or less; the possibility that such a limited test can serve as the basis for a scientific judgment seems to be small.

Also in the past, drug samples made it possible for physicians to supply free drugs to indigent patients. This need has been modified by the advent of Medicaid and other programs under which Federal and State funds may be used to provide drugs to welfare patients.

It is recognized, of course, that some physicians may wish to undertake trials of a new drug in their own practice, and that some patients are unable to obtain drugs under an available welfare or insurance program. In such cases, it has been proposed, physicians may be supplied free samples upon request to the manufacturer.

CHAPTER 7

INDUSTRY PRICES

In the mass of debate, controversy, and Congressional hearings of the past decade dealing with the drug industry, perhaps the most heated issue has concerned the attempt to determine whether drug prices are or are not "too high." Consequently, the manner in which prices are determined, the behavior of prices over time, and the price discounts to various purchasers all bear on any understanding of that controversy and on any evaluation of the various points of view heard within it.

Drug Distribution. Prescription drug companies typically promote brand-name drugs of all types to the Nation's practicing physicians, dentists and, to a lesser degree, wholesalers and retail pharmacists.

Today, there are perhaps 191,000 medical doctors and doctors of osteopathy in private practice, 110,000 dentists, and 120,000 active pharmacists. In addition, approximately 45,000 physicians are in training and 55,000 are in government service or are engaged in professional work other than private practice. (*88*)

The industry's commercial marketing of prescription drugs, however, is accomplished not through practitioners but largely through wholesalers who sell to independent and chain store pharmacies, or through direct sale to such pharmacies.

In 1966, 47.5 percent of domestic sales was to wholesalers, down nearly one percent from 1965. Direct sales to retail outlets of all types accounted for 29.6 percent, slightly lower than in 1965.

Direct sales to hospitals (private, State, and local government) and the medical profession accounted for 17.2 percent of domestic output, while the Federal government, including hospitals and other government installations, purchased 4.8 percent. Miscellaneous purchasers acquired the remaining less than one percent (*56*) (see Figure 8).

The Discounting System

Manufacturers' prices of prescription and over-the-counter drugs are found principally in *Drug Topics Red Book* and the *American Druggist Blue Book*, both standard price directories published annually. Normally, the *Red Book* and *Blue Book* listings quote the maximum price to the retailer, whether he buys from a wholesaler or directly from the manufacturer. However, *Red Book* and *Blue Book* do not reflect the actual manufacturers' prices to wholesalers and retailers, which are determined by the amounts of various kinds of discounts. Nor do these publications always reflect the prices in the most recent editions of each company's product catalog.

The price discounting system starts with the company's catalog prices. Wholesalers and retailers, hospitals, and government agencies often pay markedly different prices for the same drug and dosage form, as described later. Some prices quoted in the *Red Book* and *Blue Book* appear generally to be unchanged over long periods, though both the wholesaler and the community pharmacist are not being charged the list prices.

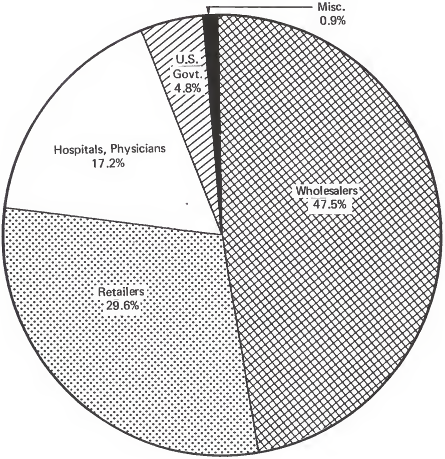
For example, about 200 drug products accounted for 67 percent of all prescriptions filled in 1966. The *Red Book* prices for one or more dosage forms of at least one-quarter of these drugs had not changed from the 1959 to the 1968 editions. (*63*, p. 71) Slightly more than one-half of the drugs with unchanging prices were brand-name products—most presumably protected by patents—made by the largest manufacturers.

The prices of most drugs on the list of 200 have fluctuated to some extent during the last decade but the disparity in manufacturers' listed prices and what their customers really pay makes reasonable comparisons extremely difficult. In this respect, various indices used by business economists and the government to measure changes in prescription drug prices are vulnerable to misinterpretation.

A number of factors may cause the disparity between some of the published drug prices and the amounts actually entered on the customer's invoice.

First, the introduction of a new dosage form can mean a price change for a drug whose other existing forms remain unchanged in price. The overall price of the product does not necessarily remain static because the price of several older dosage forms holds steady.

Figure 8.—Domestic Distribution of Human Dosage Form Prescription Drugs by Percent of Manufacturers' Sales, 1966



SOURCE: PHARMACEUTICAL MANUFACTURERS ASSOCIATION, 1968. MANUFACTURERS' SALES OF ETHICAL PHARMACEUTICALS, ANNUAL SURVEY OF PMA MEMBERS, AUGUST 1967.

Second, the catalog price is not necessarily what the company recovers overall per unit, even if it sells directly to retailers. Volume discounts, bonus goods, and other trade incentives all operate to decrease receipts per unit.

A drug company official has said:

> "Every manufacturer selling direct has his own selling plan. These plans have little uniformity or consistency but in general offer extra discounts from the net trade price. These discounts might be based on yearly volume, volume over quota or size of individual order. So far this discount structure is fairly simple. These percentage figures appear in the various catalogues." (*44*)

Discount deals can become complicated, he pointed out:

> "We run into such items as the free goods deal. Free goods of one with eleven or two with ten are common and effective promotional allowances. However, some manufacturers have lost sight of the promotional purpose of free goods deals and are using this method to undersell competition in some trade classes without the across-the-board reduction. Use of physician samples for this purpose is also common."

And he added:

> "To further complicate the picture, we have wholesalers passing on most of their discount

to the retailer, and retailers splitting their handling allowance with the hospital, all in good free competitive form in the best tradition of Robinson-Patman. A rather good description of the pharmaceutical marketplace was given by a leading professor in business administration recently when he referred to it as 'an oriental bazaar.' "

Another reason for a relative lack of apparent catalog price movement is that for products available from more than one source, the catalog price constitutes an "umbrella" beneath which the company can maneuver against competing products. The higher the umbrella, within limits, the more elbow room there is for maneuvering. (*63*, p. 71)

Pricing Factors

Generally speaking, the information considered by a drug manufacturer in pricing a new product includes direct manufacturing costs, overhead, clinical factors, marketing and distribution costs, and profit potential.

The cost of goods sold normally is less than half the selling price of a new prescription drug. Research, marketing, administration, and other overhead items must be allocated over a range of products in the manufacturer's line.

Clinical factors are based on the nature of the condition the drug is designed to treat. How many people suffer from the condition? How effective is the drug in treating it? How much of the drug should the patient take and how often? What dosage forms will be needed? What does the patient pay for existing drugs for treating the same condition? Again, some of the answers must be estimates. (*63*, p. 72)

Another factor is whether the drug is used for acute or chronic conditions in the young or the aged. Those who take drugs for prolonged periods (perhaps for life), it is contended, should be offered medication at the lowest possible cost so that it does not become too heavy a burden. In the view of some observers in the drug industry, patients suffering from chronic conditions deserve special consideration. Similarly, manufacturers have been advised to support efforts to make prescription drugs available at lower cost to the indigent, to those not gainfully employed, and especially to the aged. (*15*, pp. 58 *et seq.*)

Actually, the industry's response antedates this suggestion. For example, drugs designed to treat uncommon illnesses—where the market is limited—are often sold at or below manufacturer's cost and in some cases may be supplied without charge.

Profit potential and the cost of promoting a new drug to physicians and others are intimately related. One reason is that therapeutic value does not guarantee wide sales, at least initially. Word of therapeutic efficacy demonstrated by such products as sulfa-drugs, penicillin salts, and corticosteroids spread quickly, but these were atypical. Much more common are the chemical workhorses that provide more modest therapeutic gains—often variations of existing drug products—and they need marketing help.

A drug ideally should be priced so that it can absorb not only the costs of marketing required to realize its full profit potential, which requires another estimate, but also a large share of its research and development costs. Its price must also reflect a share of the costs of unsuccessful research.

When a drug company takes the trouble to apply for a trademark, it is usually for a drug product with high profit potential. Price and profit on trademarked drugs—along with marketing costs on them—tend to be high. Conversely, price and profit on drugs sold without a trademark tend to be low. Since established generic-name products generally are well known to the physician, they are not promoted extensively. Accordingly, the manufacturer of such products can normally offer them at low prices.

The latitude allowed a drug company in charging what the market will bear is apparently determined by the uniqueness of its product. A major breakthrough into an entirely new therapeutic field obviously will find no competitors waiting to offer a reasonable substitute. Thus, the innovator can dominate the market in that new therapeutic group, and charge what he considers appropriate until a competitor develops a more attractive product.

For products that are not unique—and this applies to the majority of innovations coming from the pharmaceutical industry—the situation is different. If comparable substitutes in their therapeutic group already exist, a firm can hope to achieve only a limited share of the market, regardless of price, unless it undertakes a heavy promotion campaign.

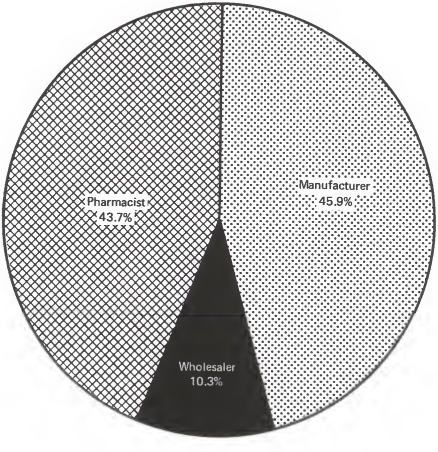
Introductory Price. When a new product is first introduced, a drug company tends to price it relatively high. It might be priced to produce a specified annual income, with anticipated price reductions, inflationary increments and competitive developments figured in, over the length of the patent life, and perhaps beyond. A relatively high initial price is encouraged by the fact that price competition at the manufacturer's price probably will account for less than half the price to the patient. (*63*, p. 73)

Figure 9 shows how an "average" prescription cost is divided among manufacturer, wholesaler, and retailer; Figure 10 indicates how the manufacturer's share of the cost is divided.

Price Increases. Although the average prescription price of an original prescription (as distinct from a refill) was $3.56 in 1966, according to the National Prescription Audit (R. A. Gosselin & Co.), the average retail price of an original prescription for a newly introduced product was $4.88, rising from $3.95 in 1962. One reason for the increase, industry sources say, is that the average price level of today's highly potent and complex drugs is higher than the average for older, less potent drugs. It has been suggested that some of the gradual rise may be due to an increase in units or tablets per prescription. This may apply to some products but not to those drugs which require constant supervision of the patient, with the writing of prescriptions at relatively frequent intervals. (*15*, p. 58) With some of the newer, more powerful drugs, the overall cost of treatment may actually be less than it was with older medications because fewer doses are required and the course of the disease is halted earlier.

The originator of a new drug usually sets the selling price on the basis of considerations already described. This price seems to become a guide for all succeeding drugs with similar therapeutic action and dosage forms. A British writer has suggested that "the pricing policy of the leader

Figure 9.—Components of Prescription Cost of $3.20 Among Manufacturer, Wholesaler, and Pharmacist, 1965 (See also Figure 11, page 55)



SOURCE: DRUG TOPICS, APRIL 4, 1966.

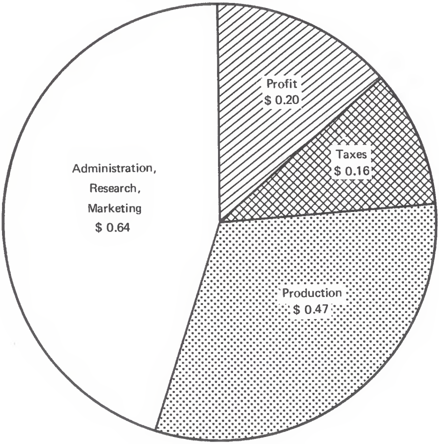
is bound to have a dominant effect on the policy of rivals." (*30*)

In general, it appears, new items appearing on the market are priced higher than the items they displace—perhaps because the new items are more potent, more sophisticated, need less frequent use, or possess some other characteristic that justifies the price differential. But it may be that the higher price is really just that—a rise in price, if not in the actual price tag, at least in what the consumer must pay for his drugs, now that he is buying the new item rather than the old.

Price Decreases. When they occur, price declines may be of different sorts and the result of different circumstances. Some of these price changes are of only academic importance to the consumer. For example, some early breakthrough drugs, such as the first antibiotics and steroid hormones, were priced originally at very high levels, reflecting their high development costs and the primitive production processes employed. As improvements in manufacturing methods occurred, prices fell—and often fell drastically. Reductions of this sort obviously are highly significant from the consumer's point of view.

Reductions of another sort are more common but may or may not be meaningful. These involve products that have been on the market longer than their actual or expected commercial life. For some of them, the price cuts may reflect the producer's recognition of their past contribution to

Figure 10.—Components of Manufacturer's Share of Prescription Drug Costs of $1.47, as Received From Wholesaler



SOURCE: HOW PATIENTS' PAYMENTS FOR DOCTORS' PRESCRIPTIONS ARE DIVIDED BETWEEN DRUG STORES, WHOLESALERS AND PHARMACEUTICAL MANUFACTURERS. ADAPTED FROM LILLY DIGEST, NATIONAL WHOLESALE DRUGGISTS' ASSN. OPERATING SURVEY AND DRUG TRADE NEWS FINANCIAL SURVEY OF DRUG TRADE SUPPLIERS, DRUG TOPICS, APRIL 4, 1966.

profits and he may thus be induced to lower these profit margins. To consumers, such reductions may be very meaningful. For others, though, the price cuts may be competitive moves—and usually futile ones—to offset the introduction of new items which threaten to displace them in the market, and thus are of less significance to patients who receive prescriptions calling for the new items.

An example of this type of price cutting was reported recently in the drug trade press, as follows:

> "Lilly, whose basic product patent on V-Cillin and V-Cillin K expires July 31, licenses both Abbott and Wyeth. Lilly sells the bulk pharmaceuticals to Wyeth, and Abbott manufactures its own bulk materials. Thus, Lilly's steady price reductions (*10 to 22.5 percent, effective June 3: Ed.*) can be regarded partly as an effort to discourage new competition from entering the market when the patent expires." (*18*)

Price Indices

The Bureau of Labor Statistics publishes an annual Consumer Price Index for nine categories of drugs encompassing 14 specially selected products. This BLS index has suggested a decline in prescription drug costs since 1957–59. But, as discussed elsewhere, a different measure is provided by three major surveys of average prescription prices of all drugs, which uniformly demonstrate a gradual rise in average prescription prices at the retail level. (*82*)

The Wholesale Price Index, also published by BLS, has shown a decline in manufacturers' prices from a level of 100 in 1961 to 90.4 in January 1968. This decrease reflects the prices of about 50 selected drugs which have been examined periodically, and which have generally remained steady or decreased in price, or in a relatively few instances have increased. But the wholesale index does not reflect the impact of the introduction of new and more expensive single or combination products or new dosage forms, which tend to raise average prescription prices. (*82*)

Substitution Effect

In any discussion of prescription drug price indices and "average prescription prices," the industry notes that cognizance must be given to the trend for newer and more effective drugs which may limit or substitute for hospitalization and, in many cases, for the time and expense of physicians and other health care personnel. Within the hospital, this substitution effect occurs not only with new products—which may shorten the duration of the patient's stay—but also through new dosage forms or methods of applicaton which economize on other costs, e.g., reducing the number of medication errors, cutting down on nursing time and otherwise increasing hospital efficiency. Despite the higher costs of some of the new substitute drugs, the drug industry maintains that the share of the total health care dollar spent for prescription drugs has declined from 11.7 cents in 1957 to 9.8 cents in 1966—a fact which the industry says profoundly affects the task of projecting future health care expenditures both in the public and private sectors.

CHAPTER 8

PATENTS, TRADEMARKS, AND COMPETITION

Earlier, it was noted, as the modern drug industry developed out of World War II, the important relationship of research and development to technical and commercial success was soon recognized. The industry quickly acquired a research consciousness that has become one of its most salient features. As new drug discoveries occurred and new areas of therapy opened, competition often was vigorous and prices tumbled.

In order to protect the results of their research and product development, however, drug firms increasingly sought strong patent protection. Also, to distinguish their own from those of rivals, the companies attached short, easily remembered trademarked names to their products. With product differentiation becoming the basis of industry competition, the promotion of individual tradenamed items to physicians—directly and almost exclusively—became the dominant form of marketing rivalry.

In any description of the essential characteristics of the prescription drug industry, therefore, a prominent place must be reserved for the "new competition"—competition in the development and promotion of differentiated specialties—that emerged in the early 1950's.

Here, it is essential to emphasize that the drug industry is, in fact, characterized by competition—and often by very intensive competition. But this is a different kind of competition. The so-called new competition of the drug industry is not the customary type observed on the market place, in which rivals compete on the basis of both quality and price, but rather a form in which the competition is based solely on quality—or claims of quality—with price considered to be of relatively minor importance or of no importance at all, and therefore deemed unworthy of mention.

To the physician who may be interested exclusively in the outcome of his prescribed therapy, quality may well be the only factor of importance. Certainly this is true in life-and-death situations. But to the patient—especially to one with a chronic disease which may require many months or years of drug treatment—the quality of the drug and the effects of treatment are important factors, but not the only important factors. Price, too, deserves consideration.

Spokesmen for the drug industry say pharmaceutical companies are as price-conscious as anyone but that they control no more than half the eventual price of a prescription—the wholesaler and pharmacist accounting for the other half. They claim, furthermore, that the wholesale cost of a drug product must be balanced against its expected therapeutic effect—an effect which may put the patient back on his feet earlier than would otherwise be possible, thus constituting a saving in time loss from his job and in his total health care costs.

In any analysis of this new competition in the drug industry, attention must be focused on the factors that condition it, its facets and manifestations, its results in terms of both therapeutic and financial effects, and the problems and controversies that have arisen regarding it. Here, probably the most important aspects are related to patents and trademarks—aspects which have long been important to many consumer product industries, but which are vital to the drug industry.

Patents play a prominent role in each of the two main features of competition in the prescription drug industry: first, rivalry in the development of new drugs and drug products; and second, in the promotion and advertising of exclusive specialties. It is the exclusive property rights afforded by patents, and the commercial benefits derived from them, that developed the first of these rivalries and set the stage for the second.

Understanding the two conflicting points of view that have arisen over patents in the drug industry is not difficult. To industry critics, the exclusivity of a patentee's right has substituted developmental and promotional competition for price competition in drug marketing. To industry supporters, the incentives and rewards offered by patent rights are essential contributors to the industry's large research and development effort, the flow of new products to which it leads, and the subsequent beneficial impact on health and life that ultimately occurs. Hence, arguments over the necessity, duration, scope, and use of patents usually involve the presentation by each side of its own point of view and rebuttals to the views of the other side.

Drug manufacturers have responded to proposals for certain changes in patent laws by warning that pharmaceutical research may wither and die without the economic protection of patents. They have also opposed changes in trademark law which would vitiate the value of brand-name identification in promoting drug products.

On the other side, it has been argued that drug makers should not be allowed to use trademarks and patents in a way that would give them control of drug markets both at the prescribing level and at the manufacturing level. It has been asserted that exclusive patents, combined with multi-million-dollar drug advertising campaigns, can keep new or small companies out of the high profit circle and effectively stifle price competition in the market place.

The Nature of Patents

A patent is a grant of legal monopoly to an inventor for a term of years—17 in this country—after date of issuance. It is a reward for achievement that has its origin in the U.S. Constitution, although the word "patent" is nowhere mentioned in that document.

The Constitution simply endows the Congress with the power "to promote the Progress of Science and Useful Arts, by securing for limited Times to Authors and Inventors the Exclusive Right to their respective Writings and Discoveries." (*11*) In essence, the right of a patent owner is a negative one, in that he has a right to deny to all others the practice of the invention discovered by him in the patent instrument. (*43*, p. 115)

When a drug maker develops a new product, he does not wait for Food and Drug Administration clearance before seeking a patent, since a competitor may be working on a similar innovation. Accordingly, the patented product may not become available to the public until several years of animal and human testing have proved its relative safety and therapeutic effectiveness. It would seem, therefore, that the patent protection in most situations may actually be less than 17 years, but on the other hand, a delay in issuance of a patent (patent pending) may actually extend the effective protection beyond the 17-year period.

Patents for all types of products and processes are flexible instruments which may be used to extend a company's control over a profitable item far beyond 17 years. Senator Estes Kefauver said in 1961 of patents in general:

> "The Congress which enacted the first patent statute in 1793 [sic] could hardly have envisioned the present corporate practice of 'portfolios of patents' blanketing an entire technology. Patents are secured on minor changes in the art; they are carefully spaced so that corporate control is never lost; they can, with ingenuity, be used to exclude the competition indefinitely." (*34*, p. 235)

It is important to note that drugs—that is, chemical entities—are patentable, as are the ways of making them. Specific drug dosage forms are not patentable.

It is also interesting to note that the definition of a patentable drug has been broadened since 1946.

Before then, naturally occurring substances could not be patented. For example, product patents on cortisone and hydrocortisone were impossible to obtain. In 1946, however, a patent was obtained on the new antibiotic streptomycin and in 1955 a patent was issued on tetracycline, another antibiotic—both obtained from naturally occurring molds.

Patent Laws Abroad. It is noteworthy that American drug companies are doing more and more business overseas, where patent laws in general offer less protection to the inventor. Among major drug producing countries, only the United States and Belgium do not have some general provision for compulsory patent licensing. (*89*) The European countries generally have taken the position that public health is of such paramount importance that patents in the pharmaceutical field are in a special category, and at times warrant exceptions from the usual treatment accorded to patent grants.

In some countries, for example, patents are permitted on processes of manufacture but not on drug products. Similarly, provision is made for compulsory licensing if the process is not being used by its inventor or if such licensing would serve the public interest or enhance the public health. Nevertheless, despite the existence of legal mechanisms, compulsory licensing has been seldom used. In Canada, it has been held, few companies have invoked the law because of the probability of lengthy and expensive litigation. In certain European and other countries, the governments have used other approaches—notably formularies and price negotiations—to assure more reasonable price levels. (*8*, p. 83)

Regardless of the existence of compulsory licensing provisions, American drug companies with large investments abroad have collected a substantial share of their corporate profits from foreign sales. (*24*) Many U.S. firms produce and sell their drug products overseas at prices lower than those at home, which have been attributed in some instances to lower production, distribution and other costs. However, some brand-name drug products made in the U.S. and exported to other countries also are sold there at considerably lower prices.

Patents and Competition. While there is often intense product competition—or product rivalry—among the large drug manufacturers, there have been a number of claims that effective price competition in the sale of many products has little impact. According to the chief economist of the Federal Trade Commission, price competition in drugs is ineffective for several reasons:

> ". . . Concentration in the production of drugs is high because of the patent privilege. And even where there are relatively many sellers, as well as many potential sellers—for example, in the case of unpatented drugs sold under generic names—effective price competition often is muted by vast advertising, promotion, and other selling efforts which differentiate in the minds of consumers the products of the largest manufacturers selling under their own brand or trade names from those of other manufacturers. Hence, manufacturers selling chemically identical drugs under generic names frequently have difficulty in selling them at any price." (*46*)

On the other hand, a spokesman for the drug industry declared in 1959:

> "The pharmaceutical patent is the basis of the competition in our industry and it is because of this competition, engendered by our patent system and nurtured by our trademark rights, that we have been able to maintain a foremost position throughout the world. Our competition is our source of strength—our source of better, ever more specific medication—and the source of high standard professional tools for the pharmacist and the physician.
>
> "Our competition must be maintained if we are to retain our leadership in these professional fields . . . Consequently, when we use our rights in the protection of our business, we are assuming . . . our proper public purpose. Our motive is not one of self-preservation but, in reality, it is the preservation of a proven system of endeavor, allowing adequate rewards in return for substantial risks taken for the benefit of the health and welfare of the population." (*43*, pp. 115–116)

Perhaps the most representative statement on the subject made by an industry leader was presented in 1961 by the President of American Cyanamid Company. He said:

> "Progress in our industry is dependent on patents. The availability of patent protection for new drugs provides the incentive to invest in research and development that has given the public the enormous benefits of drugs developed under the lash of intense rivalry. In our own case, the possibiilty of patent protection has been essential in inducing us to invest heavily in research." (*40*)

While large drug makers generally claim that patents encourage research and promote competition, representatives of some small firms have asserted that a patent may be simply an invitation to costly litigation. The only advantage of a useful patent which a small firm can take, they said, is to sell it to a larger rival, usually for a lump-sum, paid-up royalty. (*5*) Even if a small firm were willing to face the hazards of a legal contest, one company officer said, it would lack the funds necessary to introduce a new product because of the substantial capital needed to promote nationwide prescribing and to advertise the product broadly. (*54*)

But a patent attorney representing the PMA disagreed with this view. He said the patent system works against forces of business inaction that are especially strong when rivals can copy a new, successful drug product without restriction.

This consideration is especially important to the small drug concern and the newcomer to the field, he said, because the large existing firms have the advantage of established market positions, operating manufacturing facilities, active sales forces, and the goodwill of the prescribing physician and the dispensing pharmacist. But with the patent as protection, the small concern or newcomer has an opportunity to overcome these advantages and thereby challenge the established rival. (*23*)

Furthermore, the attorney contended, the patent system is the only antidote to the economic lethargy which assertedly would overcome a drug company that was not allowed to enjoy in full the fruits of its research and development activities. He said:

> "To the company more than usually successful in creating and marketing a new drug, the patent system offers an opportunity to enjoy an unusually large monetary return undiminished by free-loaders who would copy the success. With this prospect, the creative company can justify investment in the costly research, development, and marketing activity that lies behind each new drug. The possible returns are so great that these investments can be justified despite the ever-present risks of failure. In short, the forces of business self-interest are harnessed to overcome the normal business inertia that would otherwise dictate inaction." (*23*, p. 2117)

Trademarks

Unlike a patent, a trademark is not an absolute right—a monopoly—for a fixed term of years. The Lanham Act of 1946 defines a trademark to include ". . . any word, name, symbol or device or any combination thereof, adopted and used by a manufacturer or merchant to identify his goods and to distinguish them from those manufactured or sold by others." (*43*, p. 112)

Virtually all patented drugs have brand or trademark names which have been registered with the U.S. Patent Office; trademark names also may be obtained for an unpatented drug. Firms which are licensed by others to manufacture or sell patented drugs may register their own brand names. The Lanham Act states:

> "The terms 'trade name' and 'commercial name' include individual names and surnames, firm names and trade names used by manufacturers . . . and others to identify their businesses . . . ; the names or titles lawfully adopted and used by persons, firms, associations, corporations, companies, unions, and any manufacturing, industrial, commercial, agricultural or other organizations engaged in trade or commerce and capable of suing or being sued in a court of law.
>
> "The term 'trademark' includes any word, name, symbol, or device or any combination thereof adopted and used by a manufacturer or merchant to identify his goods and distinguish them from those manufactured or sold by others." (*78*)

In other words, a trademark is a brand name used on products or goods which move in trade channels. A trade name or a commercial name is a business name used by producers or others to identify their business or occupation. The mark identifies the product, the name identifies the producer.

Rights in a trademark are established by actual use of the trademark in goods moving in trade, and ordinarily the use must continue if the accrued rights are to be maintained. Without actual use, there is no right.

The primary purpose and function of a trademark is to denote the origin of the goods and to identify the source of the product to which it is applied. A trademark presumably protects the consumer from misrepresentation and protects the owner's reputation and the public goodwill which have grown up in its use.

Although a trademark cannot exist apart from its identifying function, its validity is not affected by registration. Even though a trademark registration runs for a 20-year renewable term, the advantages of registration apparently are more procedural than real. (*43*, p. 113)

Effects of Trademarks. Drug makers have a right to use a trademark and to promote with all the resources at their command those products which promise to give them at least a temporary share of the prescribing market. If a company can "monopolize the eyes and ears of the prescribing physician," an economist has said, it monopolize a share of the most important drug market.[a]

However, attracting the physician's attentio becomes increasingly expensive when more tha one firm pursues this strategy of strongly pro moting brand-name products. It soon becomes s expensive that only the larger firms have the re sources to continue. Smaller drug firms dea mostly with pharmacists and ordinarily do no bring to a physician's attention the existence o low-cost generic-name drugs, even though thes products may be selling at 90 percent less than th brand-name drugs. There are exceptions, such a some members of the National Association o Pharmaceutical Manufacturers who often emplo detail men in particular geographic regions to call on doctors with specialty products that are not patented. But these exceptions are not numerous.

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[a] See Marketing, pp. 25–28.

Some industry critics claim that a more subtle but equally effective marketing weapon used in behalf of trademarked drugs is disparagement of lower priced competitive products, notably by some detail men for large drug companies. It may be suggested, for example, that most drugs sold under generic names are somehow inferior to brand-name drugs; by reiteration of this theme, the physician may be induced to equate low price with low quality. (*9*)

The doctor is vulnerable to having his confidence in the low-priced drugs thus undermined, since he is rarely in a position to evaluate by himself the relative quality of chemical equivalents. (*84*)

Another effect of trademarks on the market place occurs when a privileged market position is retained even though a drug patent has expired. For example, the tranquilizer meprobamate is price-listed by one drug wholesaler under its generic name at $2.25 per 100 400-mg. tablets, while the wholesaler's price for Miltown is $5.85 per 100 tablets and the price for Equanil is $6.00. The generic chloral hydrate is priced by the wholesaler at $1.10 per 100 100-mg. capsules, but Noctec—a brand-name product—is listed at $4.20. Even greater price discrepancies exist for pentobarbital, a generic-name sedative, which is listed at $4.50 per 1000 100-mg. capsules, compared with the listed price of the brand-name product, Nembutal, at $17.00. (*32*)

These price differences may not be fully reflected at the retail level because the cost of the drug is but one element in the price of the prescription to the consumer, and, in most instances, the pharmacist is not generally obligated to relate his markup to the acquisition cost of the drug.

The value of a trademark may continue long after patent protection has vanished because of the long-term advertising and promotion campaigns carried on during the life of the patent. The drug industry is no different from other manufacturing groups in this respect, except that the consumer of prescription products—because of State anti-substitution laws—usually cannot shop in the market place for a less expensive chemically equivalent drug if his doctor has prescribed by brand name. Furthermore, at present, few pharmacies post the prices of prescription drugs so that customers may make comparisons before having a prescription filled. Patients can, however, ask about prescription drug prices in various pharmacies. They may save money in this manner because surveys have shown that pharmacies often charge different prices for the identical product, depending on their individual operating costs and customer services. (*26*)

Drug Patent Alternatives

The form which the "exclusive rights" of patent holders should take was left to the Congress, and the Congress may redefine these rights at any time. There is nothing sacrosanct in the present statutory term of 17 years for Letters of Patent, nor is there anything to prevent reexamination and modification of this or other provisions if it is determined that such changes are in the public interest. (*34*, p. 231)

However, Congress has not elected to enact special legislation regarding patents on drugs and other health products. Although a number of bills have been introduced since 1912 to provide for general compulsory licensing of drug patents, none has been approved.

One of the most recent efforts was sponsored by the late Senator Estes Kefauver in April 1961. The measure originally proposed to amend and supplement the patent, antitrust, and food and drug laws, but the proposals for reform affecting patent and antitrust laws were eliminated before the bill was passed in October 1962 as an amendment to the Federal Food, Drug and Cosmetic Act.

Congress has found it necessary, however, to limit a patent owner's rights in protecting his patent monopoly against the Federal government. The United States Code provides that where a patented invention is used or manufactured by or for the United States without a license, the patent owner has a cause of action in the U.S. Court of Claims for his reasonable and entire compensation. (*79*) In this situation, it has been determined that the patentee's monopoly must give way to the public interest where such interest is found to be of paramount importance.

The Defense Supply Agency (DSA) of the Department of Defense, for example, has found it necessary at times to purchase patented prescription drugs from unlicensed domestic or foreign manufacturers because the domestic patent holder's prices (and those of his licensees) were considered too high. This has occurred with purchases of tetracycline, meprobamate, and other drugs required in large quantities by the Armed Forces, the Public Health Service, and, in some cases, the Veterans Administration.

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In 1967, two suits were filed in the Court of Claims for patent infringement as the result of such government drug purchases from unlicensed manufacturers, both here and abroad. A patent infringement claim involving sulfadiazine was settled for approximately $30,000, according to the DSA patent counsel. (*80*)

To date, no formal patent infringement claims have been filed as a result of foreign purchases of tetracycline. This may be related to a jury decision in December 1967 which found three large, diversified American drug companies guilty of conspiring between 1953 and 1961 to monopolize and fix the prices of tetracycline and two chemically-related antibiotics. Two other firms were named as co-conspirators but not as co-defendants. The decision has been appealed.

A Department of Defense contract may not be awarded to a foreign manufacturer unless the acquisition cost is at least 50 percent less than the lowest bid from a "responsible" domestic manufacturer. In fiscal year 1966, meprobamate, nitrofurantoin, and several forms of tetracyclines were obtained through this procedure. These products represented only $6 to $7 million of the $221 million spent for nearly 1,400 drugs and biologicals by the DOD. (*80*)

Abolition of Patents. Virtually all of the important new drugs have come from countries providing strong patent protection, including the United States, Switzerland, Great Britain, Germany and France. (*16*)

Both in Italy and in the Soviet Union, moves have recently been made toward developing patent protection. Pharmaceutical patent legislation is now pending in the Italian Parliament, though the proposed changes are not so protective as some sectors of the industry would like. In 1965, the Soviet Union subscribed to the "Paris Convention" (International Convention for the Protection of Industrial Property), thus acknowledging the importance of patents for the U.S.S.R.'s technological progress and granting patent rights to inventors from other countries.

The drug industry maintains that without the inducement of patent protection, it is unlikely that a high proportion of the new drugs of the past 20 years would have been discovered. Drug companies say they would not have had either the incentive or the means to spend $3 billion for research and development between 1951 and 1966. (*61*)

Patents have some effect on drug prices—as they have an effect on the price of all patented articles. But, according to a recent United Nations report, patents are by no means the dominant factor:

> ". . . The effect of higher prices specifically due to patent protection is almost impossible to disentangle from higher prices due to such factors as exclusive know-how, trade secrets, restrictive practices, or the dominant market position of the supplier, all of which are intrinsically related to the patent system. Since patents are thus only one of the factors which may bring about higher prices, the question arises whether measures directly affecting price levels or general antitrust legislation are not an economically more effective and administratively more feasible technique of coping with the problem than legislation devoted specifically to the patent system." (*77*)

Some economists have proposed in Congressional testimony that drug patents be limited—or, if necessary, abolished—to promote price competition and minimize product rivalry.

A University of Houston economist, Henry Steele, suggested that a satisfactory solution to the problem of high drug prices requires a series of related reforms which would alter marketing and prescribing practices and bring about price competition at both the manufacturing and retail levels. He said the elements of such a solution would include: (*69*)

- Abolition of drug product patents, and compulsory licensing of drug process patents at reasonable royalty rates.

- Outlawing of trade names for drugs, with the requirement that drugs be identified, advertised, and sold only by use of the generic name of the active ingredient, together with the company name of the manufacturer.

- Providing the Food and Drug Administration with sufficient authority, staff, and funds to carry out a drug inspection program adequate to prevent the sale of any substandard drug.

These and other reforms were advocated by the economist, who said that if drug prices did not decline within a reasonable period of time, consideration should be given to outright abolition of drug process as well as drug product patents, compulsory licensing of patented drug imports, and price control or public utility-type regulation of the industry.

Abolition of product patents and compulsory licensing of drug making processes, he said, would increase the number of firms, both large and small, that make and sell each type of drug. This would tend to stimulate price competition, in his opinion, because small firms would sell at low prices in order to counter the initial advantage of highly advertised brands.

Limitation of drug promotion to generic name plus company name would assertedly reduce the relative appeal of drug products promoted by the large brand-name firms. This supposedly would make expensive sales promotion efforts less profitable. Since production costs are said to be low, price competition between large and small firms would eliminate much of the reason for large firms to engage in sales promotion contests among themselves.

On the industry side, the response to this kind of suggestion was made several years ago by the president of a large drug company who subsequently became a U.S. Secretary of Commerce. In 1963, he said:

> ". . . it is essential for manufacturers to have the right to use trademarks, because only in that way can a reputable firm identify itself with its own products behind which stand the reputation, the careful manufacturing procedures and quality controls, and the sense of responsibility of the firm. Obviously, no law can provide all companies with equal experience, reliability, and integrity. The trademark is the best assurance that the patient will receive exactly what the doctor ordered." (*10*)

Prescribing a product by generic name plus name of a reputable manufacturer would, of course, provide the same assurance.

In response to proposals such as those by Professor Steele, the industry points out that compulsory licensing and other remedies already are available under certain circumstances. During Congressional testimony in 1961, for example, it was noted that more than 30,000 patents of all kinds were subject to compulsory licensing under antitrust decrees. This figure exceeded the number of patents that had been subjected to compulsory licensing under the laws of all foreign countries combined. (*23*, p. 2129)

Restricted Patent Life. It has frequently been proposed that the patent on a drug should extend not for 17 years, as is the case for other discoveries or inventions, but for a much briefer period—such as 10 years, 7 years, or even 5 years.

Proponents have stated that drugs are so vital to the health of the Nation that they should not be given the standard period of protection. They have likewise claimed that most patented drugs will pay for themselves within the first 3 years after they are put on the market. (The European Economic Council has called for a patent life of 20 years.)

As a variation of this approach, it has also been recommended that the patent life on a drug be maintained at the present 17 years, but that exclusive rights to the trademark should last no longer than the patent. Thus, at the end of the 17-year period, any manufacturer would be free to market the drug under its original trademark or brand name. It has also been proposed in Great Britain that brand names for newly licensed drug products be abolished. (*64*)

Compulsory Licensing. Much discussion in recent years has been devoted to compulsory licensing under a drug patent, whereby the patent holder would be required after a specified period—such as three years after the product was introduced—to license any other manufacturer who desired to produce and market the drug on a royalty basis.

In an industry characterized by rapid product turnover and a high rate of obsolescence, three years of exclusive patent protection is said to be a reasonable period to recoup research and marketing investments and to make a profit. Numerous studies—including one by Arthur D. Little, Inc.—have shown that the greatest portion of sales of a new prescription drug product is likely to occur in the first few years after its introduction, even though many such products continue to sell and generate profits for many years after the patent has expired. (*66*, p. 1899)

If licensing were required after the first three years of a product's market life—i.e., after major recovery of investment—other firms could enter that product market by paying royalties. Price competition might then occur among these rivals. Beneficial results to consumers would be possible only for those products with a commercial life longer than three years. For these, the patent holder would continue to earn an innovator's profits, though perhaps at lower rates than before, and consumers possibly could purchase prescriptions at lower price levels.

Make-or-Sell Licensing. As yet another approach, it has been proposed that the patent holder should not be permitted to monopolize both the manufacture and the sale of a new drug, but should be required to license either other producers or other sellers. (*66*, pp. 1887–1888)

This is based on the fact that a drug patent often gives its owner a monopolistic position in two markets, bulk sales and dosage-form products. Compulsory licensing in either one of these markets would have the effect of denying monopoly profits in the other. Specifically, the manufacturer could take his profits in the sale of bulk drugs, or in royalties from licensees for its manufacture, but would have to share the market for finished products. Or he could earn substantial profits as the sole seller of finished products, but would share the bulk market with other manufacturers.

Under this plan, patent owners would earn reasonable and adequate profits by charging attractively high bulk prices or by imposing the most favorable royalty rates permitted. Since the cost of bulk ingredients is usually only a small fraction of the total cost of goods sold, high bulk costs or royalties would be more than offset by other economies—particularly reductions in marketing costs—and more reasonable profit margins that price competition might bring about.

Release of Technical Information. As part of the New Drug Application procedure of the Food and Drug Administration, the manufacturer of a new drug product is required to submit a voluminous quantity of clinical and technical information, including data on ingredients and methods of production.

FDA has held that the New Drug Application and the technical information included in it are the property of the applicant, and cannot be released—except with the applicant's consent—even after the patent has expired.

Whether or not this policy is appropriate and in the public interest has been questioned. Dr. James L. Goddard, then the Commissioner of the Food and Drug Administration, testified:

> ". . . I think properly that the question should be discussed by Congress in terms of the scientific and business community involved. Congress should get down to the issues involved here and see whether or not the interest of the public at large might better be served by a public policy which permitted disclosure of the clinical, the scientific information incorporated in New Drug Applications." (*26*, p. 748)

He indicated his belief that a modification in the present policy "would require law in this instance—a change in the law."

Closely related to the NDA issue is the question of drug information required by law to be submitted with an application for a Letter of Patent. Theoretically, most of the technical drug production information given to the FDA in a New Drug Application should also be filed with the U.S. Patent Office and made part of the public record.

Drug companies that desire to produce a drug on which the patent has expired should thus be able to obtain all the necessary information on its ingredients and the manufacturing processes. But, according to the U.S. patent officials, this is not always the case. (*34*, p. 235) The Patent Office has lacked the resources to enforce this provision of the law, and often it is found later that a key step was omitted from the array of technical steps listed in the patent application. This failure to disclose fully is a common complaint from the smaller drug producers. Even when the patent finally expires, they have claimed, great difficulties are encountered in unraveling the technical procedures of production, and considerable expense may be involved.

The "know-how" of a drug company, however, often consists of technical knowledge and equipment innovations that give it an edge over competitors. Under cross-licensing agreements existing today—with each licensee marketing the same drug under its own trademark—there is little reason not to share the "know-how". Without trademark protection, on the other hand, companies which license others to produce certain drugs might be less inclined to reveal their production innovations or "trade secrets."

CHAPTER 9

PROFITS AND RISKS

From the viewpoint of the drug firm as a business enterprise, the impact or success of its research and development, manufacturing, marketing, and pricing efforts traced to this point is measured largely by the profit that results from their combined influence. From society's point of view, reasonable profits are necessary if the firm is to remain in existence—if it is to continue to engage in the production and improvement of the goods and services that society wants produced. Consequently, profits must be adequate to provide this important inducement. But profits may also be at a level not justified by need, risk, function or any of the other usual criteria of reasonableness.

If, as contended by many, prescription drug prices are too high because they provide unnecessarily and unjustifiably large profits as well as being inflated by wasteful cost elements, then an examination and analysis of the profit performance of the industry bears directly on the reasonableness of drug prices.

Measurement

In consideration of drug profits, various measuring concepts have been utilized with frequently confusing results.

Thus, profits may be measured in dollars with a high degree of accuracy. This approach, however, tells little if anything about the financial performance of the drug industry in comparison with others of different size, investment, products, or sales volume.

Similarly profits may be considered on the basis of percentage of sales. But, because of differences—and sometimes very large differences—among their turnover, or sales-to-capital, ratios in different companies, this method likewise may only confuse the issue. Thus, in an industry with an annual sales-to-capital ratio of 25, for example, a 1 percent profit per sales dollar is equivalent to a 25 percent return per year on invested capital. But in another industry with a sales-to-capital ratio of five, a 3 percent profit per sales dollar would yield only a 15 percent return per year on invested capital.

Since the most important aspect to stockholders is generally the success of their investment in a company, probably the most useful measure of profitability is neither total dollar profits nor profits as a percentage of sales, but the rate of profit based on invested capital.

Profitability

Inter-industry profit comparisons are available from many sources. Despite small differences in concept, they bear a high degree of consistency in their essential findings.

Data from one of these sources—the First National City Bank of New York—show that the "drugs and medicines" industry has ranked first, second, or third each year between 1956 and 1966 in regard to after-tax income as a percentage of net worth. In six of these years, it ranked first, in three it ranked second, and in two it ranked third among the 41 industries in the study. In the years 1952–1955, the performance of the drugs and medicines industry moved from ninth to fifth among the 41, and the profitability percentages for the industry have consistently been well above the average of the 41 (see Table 4). Furthermore, the profitability of prescription drug manufacturing is probably understated by these data, insofar as nonprescription drug making activities are included and also because the profit records of diversified prescription-drug firms are toned down by the usually lower rates of earnings resulting from other lines of activity. In any case, there can be little argument that, from the investor's point of view, the business of making and selling prescription drugs is highly and quite consistently profitable. (*20*)

(For the ratio of profits to sales, the First National City Bank figures are shown in Table 5.)

Other data support this conclusion. For example, drugs were at the top of the list in 1967 among 31 major industries whose overall profitablity was measured by the national business publication *Forbes*. (*22*, p. 32) Pharmaceuticals produced an 18.8 percent return on equity, compared with an in-

Table 4

Net Income After Taxes as Percentage of Net Worth Among 41 Manufacturing Industry Groups, 1952–1966 [a] [b]

Year	Leading industry	Profit as percent of net worth	Drugs and Medicine		Average of 41 groups (in percent)
			Standing	Profit as percent of net worth	
1966	Soft drinks	22. 3	3	21. 0	14. 1
1965	Autos and trucks	23. 4	2	21. 2	13. 9
1964	Soft drinks	20. 1	3	19. 8	12. 6
1963	Autos and trucks	19. 6	2	18. 7	11. 6
1962	Autos and trucks	19. 4	2	17. 8	10. 9
1961	Drugs and medicines	18. 4	1	18. 4	9. 9
1960	Drugs and medicines	20. 4	1	20. 4	10. 6
1959	Drugs and medicines	21. 9	1	21. 9	11. 6
1958	Drugs and medicines	21. 9	1	21. 9	9. 8
1957	Drugs and medicines	24. 0	1	24. 0	12. 8
1956	Drugs and medicines	22. 4	1	22. 4	13. 9
1955	Autos and trucks	29. 1	5	18. 3	15. 0
1954	Aircraft and parts	27. 4	6	15. 8	12. 4
1953	Aircraft and parts	21. 0	8	13. 7	12. 5
1952	Autos and trucks	18. 5	9	14. 0	12. 3

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[a] Source: First National City Bank, New York City.

[b] Note: 1952–59 based on net assets, 46 industry groups; industry group titles revised starting in 1960 to conform more closely to Standard Industrial Classification; figures for most groups still generally comparable.

Table 5

Net Income After Taxes as Percentage of Sales Among 41 Manufacturing Industry Groups, 1952–1966 [a] [b]

Year	Leading industry	Profit as percent of sales	Drugs and Medicine		Average of 41 groups (in percent)
			Standing	Profit as percent of sales	
1966	Drugs and medicines	10. 8	1	10. 8	6. 3
1965	Drugs and medicines	11. 0	1	11. 0	6. 4
1964	Drugs and medicines	10. 8	1	10. 8	6. 1
1963	Drugs and medicines	10. 2	1	10. 2	5. 7
1962	Cement	10. 8	2	9. 8	5. 5
1961	Cement	11. 2	2	10. 5	5. 2
1960	Cement	11. 7	2	10. 7	5. 5
1959	Cement	16. 3	2	11. 6	5. 8
1958	Cement	16. 1	2	11. 4	5. 2
1957	Cement	15. 5	2	11. 7	5. 9
1956	Cement	16. 4	2	11. 9	6. 0
1955	Cement	16. 5	3	10. 5	6. 7
1954	Cement	15. 3	3	9. 2	5. 9
1953	Cement	12. 3	3	8. 1	5. 3
1952	Cement	11. 9	3	8. 4	5. 4

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[a] Source: First National City Bank, New York City.

[b] Note: 1952–59 based on net assets, 46 industry groups; industry group titles revised starting in 1960 to conform more closely to Standard Industrial Classification; figures for most groups still generally comparable.

dustry median of 12.1 percent. The drug industry's average return of 18.1 percent on capital was unmatched; it compared impressively with the 31-industry median of 9.7 percent.

In 1967, half of the 10 drug companies on *Forbes*' "Trend Yardsticks" managed to show at least modest improvement in earnings compared with the average of their 1965–1966 earnings per share. The earnings of the 10 drug companies studied by *Forbes* were up 7 percent, compared with 13 percent in 1966 and 21 percent in 1965; sales increased about 10 percent, compared with 18 percent in 1966 and 15 percent in 1965. (*22*, p. 76)

In Table 6 are examples of financial data on major producers of ethical drugs reported recently by *Forbes.*

Table 6

1967 Financial Data on Ten Prescription Drug Producers

Company	Return on stockholders' equity (in percent)	Latest 12 months (in millions)		
		Total assets	Revenues	Net income
Abbott	15. 7	$249	$289	$25. 5
Lilly	18. 8	320	400	53. 6
Merck	26. 0	373	443	80. 8
Parke, Davis	15. 5	300	240	23. 3
Pfizer	18. 7	619	631	57. 5
Richardson-Merrell	21. 1	256	245	21. 0
Smith Kline & French	34. 4	186	257	41. 6
Sterling	24. 5	280	441	43. 2
Upjohn	17. 3	270	268	26. 5
Warner-Lambert	21. 6	432	639	52. 6

Source: *Forbes,* January 1, 1968.

Information supplied by the First National City Bank also gives a picture of long-run drug industry profitability. Since 1950 average net profits based on net worth of drug manufacturers have dropped below 14 percent only once. For half of the years between 1950 and 1966, these profits amounted to at least 20 percent. In all other years, except for 1953, they ranged between 14 and 20 percent. In the quarter-century before 1950, the industrial group which included drugs had profits consistently higher than the average for all manufacturers. (*20*)

Prospects for the future continue to be attractive, according to leading investment analysts:

> ". . . We continue to believe that the drug industry offers outstanding growth potential and that at current levels shares of many companies within the ethical and balanced drug group offer above-average potential for growth portfolios." (*45*)

Comparable data are not available on the profitability of the small drug companies which are members of the National Association of Pharmaceutical Manufacturers. According to an Association official, a profit margin of 7.5 percent based on sales would be a reasonable estimate. (*63*, p. 66) The ratio of profits to investment is not known.

Risk

With an abundance of such data, the high profitability of drug manufacturing seems obvious, at least for the industry as a whole. Furthermore, the stability of the industry's aggregate profit record is based on a fairly stable and high profitability rate company-by-company. Faced with this record, representatives of the leading firms and of the Pharmaceutical Manufacturers Association time and again have found themselves challenged by arguments that label such profit levels as excessive, exorbitant, or the results of monopolistic market power.

The main points of defense or explanation used by company or industry spokesmen usually relate in one way or another to "risk".

Economists testifying on behalf of PMA told a Senate Subcommittee that prescription drug companies face five particular risks:

- The possible development of a competing product superior to one of the company's major products, causing its virtually complete replacement in a short time.

- The possible discovery of unanticipated side-effects for a drug, leading to immediate limitations on the clinical indications for which it may be prescribed.

- The possible discovery that a drug can be misused in ways that create a significant social problem, leading to limitations on its marketability or even removal from the market.

- The possible withdrawal or restriction of a drug by the Food and Drug Administration until additional required evidence of safety or efficacy is produced.

- The possible development of a quality control problem which necessitates withdrawal of a product from the market until the problem is identified and eliminated. (*42*)

Any of these problems, the industry claims, may cause a prescription drug maker to lose hundreds of thousands or even millions of dollars invested over several years in research, product development, and marketing.

Whether risks of this sort are peculiar to the drug industry may be questioned; more important, however, is whether these hazards are based on actual experience or are merely conjectural, and whether such risks—to whatever extent they make their presence felt—truly have an impact on company profitability, or can be cushioned by appropriate planning.

Other spokesmen for the industry have added the "intrinsic value of the item" and "growth industry" arguments to the risk argument in defense of the industry profit record. In testimony before the Monopoly Subcommittee, the President of the PMA stated: (*71*, p. 1420)

> "Much has been made and continues to be made of the question of drug industry profits. Some, who on the one hand praise the pharmaceutical industry as the source of life-saving, health-giving drug products, on the other hand accuse it of making unconscionable profits at the expense of the ill and elderly. . .
>
> "We agree that the profitability of the drug industry is above average. We say this is not a unique phenomenon. It is one which characterizes rapidly growing industries generally where there is a high rate of new product innovation. Other innovative growth industries today, such as aerospace instruments and photographic goods, office equipment and computers, also return higher than average profits on capital invested. . .
>
> "We hold that the industry's profits are healthy and desirable. They provide the incentive to manufacturers to continue to operate their businesses the way they do, and the incentive to others to invest capital and resources in such companies.
>
> "In this high-risk industry, a high rate of profit is essential to attract the capital and other resources necessary to achieve further breakthroughs in medical progress. . .
>
> "The stuggle within the industry for success—the competition to be first with the new drug discovery—is costly and risky. Without the profit incentive, it could not be continued. If it stops, the public will be the loser."

There is abundant evidence that the development of an individual drug may be associated with a high degree of risk, and that any such development is an economic as well as a scientific gamble. There is, however, no such evidence that this kind of risk characterizes a major drug company with a substantial line of products. When such a company undergoes a painful loss in this kind of a gamble, the record would seem to show, it generally covers it by substantial profits on other drugs.

Some short-line, specialty drug houses with relatively few products can be hurt economically when a top seller in their line is supplanted by a competitor's innovation. However, there is no indication—at least during the past 20 years—that losses of this nature have forced any major pharmaceutical manufacturer out of the drug business. The worst that can happen, apparently, is a short-term reduction, usually slight, in net income.

In regard to this central issue of risk, one economist says of the drug industry:

> "The high profitability reflects the absence of competition: the stability of profits demonstrates the absence of risk to investors.
>
> "If risk were to exist, one would expect to see the high gains of some firms accompanied by occasional losses—to themselves or others—but such evidence of risk is virtually nonexistent." (*66*, p. 1880)

The industry has made few if any concessions on this point of risk. For example, a study of economic risk and return in American industry, sponsored by the PMA, was reported to a Senate Subcommittee by Arthur D. Little, Inc., in consultation with economists Jesse W. Markham and Paul H. Cootner. Using a definition of risk developed by Gordon Conrad and Irving Plotkin, the report claimed that the prescription drug industry in the United States assumes a greater proportion of economic risk-taking than do most industries because of the unique nature of its primary markets. (*62*) The principal contention of these economists was that prescription drugs rapidly become obsolete and that the continual search for new pharmaceutical products makes speculative, costly research a day-to-day necessity.

herefore, they said, the drug industry must pro- uce an exceptionally high level of profit to obtain steady supply of capital to finance its research nd development operations.

Leonard Schifrin has challenged the logic of the ontention that "profits" supply the funds to inance research and development, stating that rofits, by definition, are the residual left after all osts—including those for research and develop- nent—have been met, and thus the argument that rofits must contain an element to pay for research s fallacious. (*67*)

Others have challenged the PMA claim that the prescription drug industry is a uniquely high-risk industry, and that high risks and high profits show a strong correlation.

Using a different definition of risk than that in the PMA study, Irving Fisher and George Hall of the Rand Corporation concluded that the "risk premium" for drugs is very low and, consequently, accounts for a very small portion of the high profits of drug companies. (*21*) To them, the explanation for the industry's high profits must lie in other factors. In their report, they demonstrated that, for the period 1959–1964, drug companies earned an average of 18.3 percent on investment, of which only 1.6 percent could be attributed by them to the factor of risk. (*46*)

Commenting on the directly-related matter of the safety and attractiveness of drug industry securities, Willard F. Mueller, Chief Economist of the Federal Trade Commission, offered the consensus of a number of leading investment houses:

> "There is no reason to conclude, on the basis of advice being given by investment analysts, that the drug industry is a uniquely risky industry. On the contrary the generally glowing reports of investment analysts suggest that large drug companies should have little difficulty obtaining adequate capital should they choose to go into the market for it. Actually, however, their profits are so large that drug companies seldom need go to the capital market for equity capital. And there is no reason to expect that drug companies would have difficulty getting adequate capital even if they enjoyed profit rates comparable to most other American industries." (*46*, p. 1816)

According to an industry observer, the ratio of product risks to economic return has diminished in recent years because of certain trends: (*15*, pp. 55–56)

- The number of new drugs introduced annually has declined in most years since 1957, and there has been a marked decrease each year between 1961 and 1967 in the introduction of new single drugs. The quality of drugs offered, however, has improved in that time and consequently drug longevity in the marketplace has increased. Drug companies are spending more money on research than ever before, but at the same time they are earning more money for longer periods with products that have been well tested before they are marketed.

- The industry has been relieved of some pressure to spend its research resources on so-called "me-too" drugs and duplicative drug products because of more stringent requirements for a New Drug Application imposed by the Food and Drug Administration. In the past, introduction of such products frequently resulted in substantial losses.

- With improvements in drug quality and salability, there is less need today to consider product losses in selling-price calculations. As in any industry, replacement of a money-making product by a competitor's innovation is a constant risk and a fact of business life. Generally speaking, however, prescription drug company operations have become even more stable than in the past, and are more conducive to long-term planning.

Thus, it seems, many objective observers of the drug industry do not believe it is particularly risky, but the argument goes on because the interested parties apparently cannot agree on what constitutes "high risk" or a "fair profit."

As far as the Pharmaceutical Manufacturers Association is concerned, risk is not the only factor related to eventual return on investment. Also cited is the "high correlation in American industries between rates of return and (a) rates of growth in product demands as well as (b) R & D to sales ratios." (*72*)

The definition of "fair profit," of course, depends on whether the person defining the term is within the industry or outside. Testimony given at recent Congressional hearings by drug company spokesmen has stressed the increasing cost of research and development during a time of decreasing productivity, while spokesmen for consumer groups have pointed to alleged discriminatory pricing practices by drug companies as evidence of high profits obtained at the patient's expense.

CHAPTER 10

FUTURE PROSPECTS

Many factors are expected to influence the growth of the prescription drug industry:

- A steady increase in the number of people in the United States, and their anticipated growing affluence, will maintain the growing demand for prescription drugs.
- The proportion of Americans over the age of 65, whose drug purchases are higher than average, is expected to increase more rapidly than the population as a whole, again contributing to an increased demand for prescription drugs.
- Higher health standards and living conditions in other parts of the world, especially in the developing nations, are expected to create important new markets for the prescription drug industry, including the American companies which are already developing important foreign markets.
- Drug research may be expected to yield new products which will make possible the control of conditions or diseases which are currently uncontrollable. Although such breakthrough developments will probably be infrequent, they, too, will contribute to increasing demands for pharmaceutical products.
- Through broader health insurance coverage, or increasing outlays for medical care by government agencies, more people will be better able to pay for drugs they need.
- Unlike many other industries, the drug industry will presumably continue to be protected from most economic ups and downs, since the need for drugs is relatively unaffected by swings in a nation's economy, and thus drug consumption can rarely be postponed.

The growth in demand for drugs may be considerably greater than the four percent-a-year expansion likely in the overall economy. As the Department of Commerce predicted recently: (*81*, p. 135)

> "The evergrowing demand for drug products reflects: rising health standards; the increase in the aging population whose drug needs tend to be greater and more frequent than those of lower age groups; and the broadening use of drugs found to be useful in conditions which formerly failed to respond to drug therapy. These should continue to contribute to the growth of the drug industry, even with fewer new product introductions than in the high output era of the fifties and early sixties."

The Department concluded:

> "With increasing pressure to make the dispensing of generic drugs in welfare health programs mandatory, the market penetration of generics, which already has gained some ground, is expected to achieve greater momentum in 1968 than ever before. Since generics normally command lower prices than their brand name counterparts, the industry is keenly aware of the problem it faces in maintaining profits at their historically high levels.
>
> "As a countermeasure, the industry has been shoring up its profitability structure by intensifying its drive toward diversification, venturing into both related and unrelated fields of activity, including electronic medical instrumentation, cosmetics, animal health products, hospital products and equipment, toiletries, foodstuffs and other household products. In addition, the industry is accelerating overseas expansion."

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PART B

THE DRUG DISTRIBUTORS

FOREWORD

Drug distributors are professional individuals and business or institutional operators who link the producers of drug products (the pharmaceutical manufacturers) and the patients who consume them. They include drug wholesalers, community pharmacies, hospital pharmacies, mail order pharmacies, and dispensing physicians.

A physician who, in the ordinary practice of his profession, writes a prescription order for his patient who in turn takes it to his neighborhood pharmacy in order to receive the medication is not a drug vendor. Nor is the physician who administers drugs directly to his patients in the ordinary practice of medicine, but if he actually dispenses or directly supervises the dispensing of the drug product to the patient for home use, the physician is a drug vendor.

Historically, drug products have moved from the manufacturer to the consumer through both wholesale and retail markets. The drug wholesaler consolidates large quantities of drug manufacturers' trade packages, and distributes them in smaller quantities to retail distributors. Wholesalers have also brought economic benefits to both manufacturers and retailers. The manufacturers are able to reduce their drug inventories by shipping large quantities directly to the wholesalers. Retailers benefit both from reduced inventory levels and from the credit extended to them by the wholesaler, thus allowing for smaller capital investments.

The post-World War II era has seen some shift in the wholesale distribution of drug products. Many drug manufacturers now distribute their products not only through wholesalers but also through direct sales to some drug retailers.

For many years, small, independently-owned neighborhood pharmacies dominated the distribution of drugs to the patient. Before World War I, about 90 percent of all prescriptions dispensed were compounded from bulk drugs. Today almost 95 percent of all prescriptions are prefabricated by the manufacturer. After World War II, other retail institutions expanded into the traditional domain of the pharmacist. Today, hospital outpatient dispensing, increased chain drugstore activities, physician-owned pharmacies, and other retail outlets all share the outpatient prescription market with the independent pharmacy. At the same time, pharmacists are assuming new roles which contribute to the improved quality of health care.

Distribution Costs

Unfortunately, information on the cost of distributing prescription drugs is incomplete, and extensive study in this area is needed. Available information indicates that the manufacturer gets about one-half of the consumer's prescription dollar and the wholesaler takes nine percent (direct manufacturer-to-retailer distribution costs are no less than those of full-line drug wholesalers); and the community pharmacy gets about 40 percent (Table 7, Figure 11). Wholesalers' and retailers' costs, then, take about one-half of the patient's prescription drug dollar.

Much of the material used in this section is drawn from the *Census of Business, 1963*, and from the trade literature. Unfortunately, much of the data does not distinguish between distribution costs for prescription drug products and those for nondrug products which are found in many drug outlets, both retail and wholesale.

Table 7

Distribution of Patient's Prescription Dollar [a] [b]

Patient payment to pharmacy	$1.00
Pharmacy	
Expenses	0.34
Profit	0.06
Payment to wholesaler	0.60
	1.00
Wholesaler	
Expenses	0.07
Profit	0.02
Payment to manufacturer	0.51
	0.60
Manufacturer	
Expenses	0.40
Profit	0.11
	0.51

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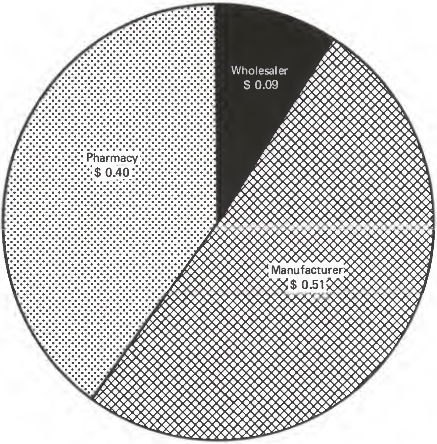
[a] Source: Lilly, Eli, and Co.: "Lilly Digest, 1966," Indianapolis, Ind., 1965; National Wholesale Druggists Association: "National Wholesale Druggists Association Yearbook," New York, 1966.

[b] Profits shown before taxes.

Figure 11.—Distribution of Prescription Dollars (See also Figure 9)



SOURCE: ELI LILLY & CO., LILLY DIGEST, INDIANAPOLIS, 1966, p. 2; NATIONAL WHOLESALE DRUGGISTS ASSOCIATION, NATIONAL WHOLESALE DRUGGISTS ASSOCIATION YEARBOOK, NEW YORK, 1966

CHAPTER 11

DRUG WHOLESALERS

Introduction

Drug wholesalers offer drug products to drug retailers and other institutions for resale or for use in the operations of a business, such as a hospital or clinic. Included among them are merchant wholesalers, who take title and possession of the products they sell, and agents who ordinarily do not handle these products directly. Most marketing authorities also include manufacturers' branch warehouses as drug wholesalers because they perform most of the functions of regular wholesalers.

The *1963 Census of Business* reports almost 4,000 drug wholesale firms. (*35*, p. 1–7) Not all of these actually distribute prescription drug products. Some sell only nondrug products, such as cosmetics, which are frequently sold in drugstores. These firms are classified as drug wholesalers because of the customers to whom they sell. The Census reports do not indicate the total number of wholesalers of prescription products, although they do give some information on the total sales volume of various commodity lines for some of the wholesalers. From these figures, it is possible to estimate the proportion of wholesalers who can be classified as prescription drug distributors. As Table 8 shows, about 50 percent distribute prescription drugs. It should be noted that not all wholesale outlets reported sales by product line. The actual number selling prescription drug products may be greater than the 1462 indicated in Table 8.

Table 8

Drug Wholesalers Reporting Drug Product Sales, 1963 [a]

Type of Outlet	Number of outlets reporting commodity lines	Number of outlets reporting drug product sales	Percentage
Merchant wholesalers	2, 389	1, 123	47. 0
Manufacturers' sales branches and offices	418	308	73. 5
Agents	159	37	23. 3
Total	2, 966	1, 462	49. 5

[a] U.S. Department of Commerce: "Census of Business," U.S. Government Printing Office, Washington, D.C., 1963.

The total drug wholesale market—including all types of drugs and other drugstore items—reached $6.9 billion in 1963, up 16 percent from 1958 (Table 9). While their share of the total drug wholesale market increased from 47.5 percent in 1958 to 52.2 percent in 1963, the merchant wholesalers' portion of the pharmaceutical market has shown a steady decline in recent years. For example, drug manufacturers sold 58.6 percent of their output to wholesalers in 1954 but only 48.4 percent in 1965 (Table 10). While manufacturers' sales to community pharmacies increased slightly during that period, most of the shift in sales was from whole-

Table 9

Number of Establishments and Sales of Drug Wholesalers, 1958 and 1963 [a]

	Number of establishments		Sales	
	1958	1963	1958 (millions)	1963 (millions)
Merchant wholesalers	3, 065	3, 321	$2, 841	$3, 619
Manufacturers' sales branches	520	441	2, 841	2, 833
Agents	212	207	290	479
Total	3, 797	3, 969	$5, 972	$6, 931

[a] Source: U.S. Department of Commerce: "Census of Business," U.S. Government Printing Office, Washington, D.C., 1963.

Table 10

Drug Manufacturers' Distribution Patterns, 1954 and 1965 [a]

Customers	1954		1965	
	Sales (millions)	Percent of total manufacturer sales	Sales (millions)	Percent of total manufacturer sales
Wholesalers	$733. 1	58. 6	$1, 344. 5	48. 4
Community pharmacies	368. 4	29. 4	840. 4	30. 2
Hospitals and physicians	117. 9	9. 4	550. 7	19. 8
Federal government	29. 0	2. 3	22. 1	0. 8
Other	3. 6	0. 3	21. 6	0. 8

[a] Source: Pharmaceutical Manufacturers Association: "Prescription Drug Industry Fact Book," Washington, D.C., 1968, p. 12.

salers to hospitals and physicians. The increased portion of sales through merchant wholesalers comes not from pharmaceuticals, but from other drugstore items.

Merchant Wholesalers

Merchant wholesalers can be grouped into three categories: full-line wholesalers, specialty drug wholesalers, and wagon distributors or truck jobbers.

Full-line Wholesalers. In 1963, there were 398 drug wholesalers who stocked and distributed the full armamentarium of prescription drugs produced by all the major and some of the smaller drug manufacturers. In addition, they stocked most of the other nonprescription items carried by most pharmacies, such as over-the-counter (O–T–C) drugs, toiletries, health aids and sundry items. The average full-line wholesaler maintained an inventory of about 30,000 items which were valued at close to $265,000 in 1963. (*35*, p. 1–11) Prescription drug sales accounted for about one-third of their total sales volumes.

Some of the full-line wholesalers have developed their own line of prescription drug products which they market under their own name. The largest wholesale drug firm in the nation produces its own line of prescription as well as O–T–C drug products which it promotes along with other brand-name products. Other wholesale firms market products under their own labels but do not engage in the actual production of the products, buying them instead from drug manufacturers.

Full-line wholesalers assemble large quantities of needed items in their warehouses for distribution to community pharmacies, hospitals, and other institutions in small lots, and some may sell many items as single units—for example, a single tube of toothpaste. Buying in such small units allows the retailer to maintain only a minimal inventory and thereby reduces his capital investment requirements. Many wholesalers provide daily or multiple daily deliveries to retailers in their immediate areas, further reducing the need of the retailer to have a large inventory, especially in prescription drug products. At the same time, selling in such small units increases the cost of wholesaling.

With operating costs increasing, many full-line wholesalers are attempting to induce pharmacies to purchase in larger quantities, and to accept less frequent deliveries.

Full-line wholesalers also provide a wide range of customer services. Most sales made by these wholesalers are on credit, and the retailer can operate on a smaller investment than if all products were purchased directly from the producer.

Full-line wholesalers also provide a host of management aids for their customers. They may offer the pharmacist help in selecting a site for a store, designing its layout, modernizing its facilities, maintaining inventory control, and developing accounting techniques. These services are usually provided without direct charge. Most wholesalers maintain some type of arrangement with fixture manufacturers and may benefit economically from the sales of fixtures to newly-established or remodeled drugstores.

The full-line wholesalers make 92.9 percent of their sales to retailers, with the small-to-medium sized pharmacies as their principal clients. (*35*, pp. 4–11) In contrast, large drugstores purchase about 50 percent of their products from wholesalers, preferring to buy the rest directly from the manufacturers. The remaining wholesaler sales are made to hospitals, other wholesalers, and other buyers, such as export firms (Table 11).

Table 11

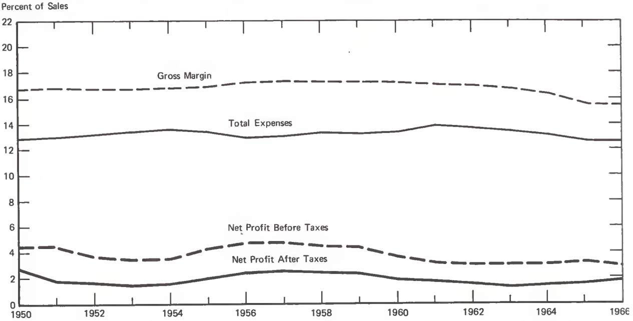
Distribution of Wholesalers' Sales to Various Purchasers, 1963 [a]

	Number of firms	Percentage of sales				
		Industrial users	Consumers	Retailers	Wholesalers	Export
Merchant wholesalers:						
Full-line	398	5. 8	0. 1	92. 9	1. 1	0. 1
Speciality	2, 923	15. 0	0. 9	68. 2	12. 8	3. 1
Total	3, 321	10. 1	0. 5	81. 2	6. 6	1. 6
Manufacturers' branch offices	441	25. 6	0. 1	48. 5	24. 3	1. 5
Agents	207	12. 9	(b)	38. 9	46. 1	2. 2

[a] Source: U.S. Department of Commerce: "Census of Business," U.S. Government Printing Office, Washington, D.C., 1963, Vol. 4, pp. 4–1, 5.

[b] Less than 0.005 percent.

Figure 12.—Summary of Drug Wholesaler Operations as Percent of Sales, 1950–1966



SOURCE: NATIONAL WHOLESALE DRUGGISTS ASSOCIATION, NATIONAL WHOLESALE DRUGGISTS ASSOCIATION YEARBOOK, 1950–1966, NEW YORK

The wholesalers' mark-up on their products is normally based on a percentage of wholesale selling price, ranging between five and 20 percent. The average markup in 1966 was 15.3 percent of sales. (*30*) Full-line wholesalers are experiencing a decrease in gross margins, from a high of 17.3 percent of net sales in 1950 to a low of 15.3 percent in 1966. At the same time, net profits as a percent of net sales have declined from 4.1 percent in 1950 to 2.9 percent in 1966 (Table 12, Figure 12).

Table 12

Full-Line Drug Wholesalers' Margin, Expense, and Profit Percentages for Selected Years, 1950 to 1966 [a]

	Percentage of net sales					
	1950	1955	1963	1964	1965	1966
Gross margin	17. 1	17. 3	16. 6	16. 1	15. 6	15. 3
Operating expenses	12. 9	13. 3	13. 5	13. 0	12. 4	12. 4
Net profits (before taxes)	4. 1	4. 0	3. 1	3. 1	3. 1	2. 9

[a] Source: National Wholesale Druggists Association: "National Wholesale Druggists Association Yearbook," New York, 1953, 1955, 1963, 1965, 1966.

The decreasing gross margins have apparentl also affected the return on investment for merchant wholesalers. Net profit as a percent of total assets had fallen from 7.7 percent in 1957 to 4.8 percent by 1964. (*30*, 1961, 1963, 1965) The decline has continued since that time. From limited data it appears that net profit as a percentage of net assets is relatively stable at about 9 percent.

Before 1965, there was little horizontal integration of full-line wholesalers. Foremost-McKesson, the largest of the drug wholesalers, has 87 individual outlets. The 1963 *Census of Business* reports that of all merchant wholesalers, 2,831 firms operated one or two establishments and only seven firms operated more than 26 outlets each. Several recent mergers, however, indicate a trend towards integration.

Specialty Wholesalers. Specialty or short-line drug wholesalers offer only a limited selection of products found in community pharmacies. Among the nearly 4,000 drug wholesalers of al types, there were 2,923 specialty firms in the U.S in 1963, with total sales of almost $1.8 billion. (*35* p. 1–11) Some specialty firms stock only prescription drugs, others stock only toiletries and cosmetics, while still others limit their stocks to drug sundries. The number stocking prescription products is unknown, but statistics indicate that th number is less than half of all specialty drug wholesalers.

The number of short-line drug wholesalers increased from 1958 to 1963 by seven percent, while the number of full-line wholesalers increased by 12 percent. Sales by both types of wholesalers increased by about 28 percent each. Specialty wholesalers generally offer both credit and frequent deliveries to their clients. Because of the limited line of products offered, however, operating expenses equaled 17.5 percent of sales in 1963. Profit information is unavailable.

While specialty wholesalers sell primarily to retailers, they also sell in large amounts to other wholesalers (13 percent) and to industrial users (15 percent), thus providing a needed storage and distribution system for other drug product users (Table 11).

About 70 percent of full-line and specialty wholesalers reported sales by commodity lines in the 1963 *Census of Business.* Of these 2,389 firms, 1,123 (47 percent) indicated sales of prescription drug products totaling $1.3 billion. Since all full-line wholesalers handle drug products, the data indicate that less than 40 percent of all specialty wholesalers are engaged in the sale of prescription drug products. (*35*, p. 8–2)

Wagon Distributors. Wagon distributors, or truck jobbers, are merchant wholesalers who carry their inventory of products in a truck or van. They make calls upon their customers and fill the orders out of the truck inventory, usually selling on a cash basis. There were 59 such jobbers in 1963, with sales of slightly more than $7.4 million. Their operating expenses equalled 17.5 percent of sales. Total wagon distributors' sales of prescription drug products, if any, cannot be determined from available information. These outlets play a relatively minor role in the distribution of drug products.

Manufacturers' Sales Branches

Many of the major drug producers maintain branch offices for the distribution of their own products. These organizations function similarly to specialty drug wholesalers and are generally classified as wholesale establishments. There were 441 such sales branches in 1963, with total annual sales of $2.8 billion (Table 9). While the total number of these establishments declined from 520 in 1958 to 441 in 1963, the annual sales volume remained almost constant. Of the 418 firms reporting on commodity sales, 308, or 73.6 percent, reported sales of prescription drugs. Apparently, the other 110 firms deal in drug sundries and other drugstore products. Prescription drug product sales by these outlets amounted to $1.5 billion.

Ninety-three of the manufacturers' sales offices do not maintain inventories. Shipment of products to purchasers are made either from larger central warehouses, or from merchant wholesalers located near the buyer. These firms had an average operating expense of 8.3 percent in 1963. (*35*, p. 9–85) Manufacturers' branch offices with stocks showed operating costs of 15.5 percent of sales, or about the same as for full-line wholesalers.

These firms make less than half their sales to community pharmacies, with 25 percent of their sales going to other purchasers—mostly hospitals—and 24 percent to other wholesalers (Table 10). To a great extent, these organizations serve as industrial or wholesalers' wholesalers. Firms with inventories provide both a credit and delivery service for their customers. Some also provide management aids.

As indicated earlier, manufacturers apparently are increasing their direct sales of prescription drug products to community pharmacies and to hospitals. Manufacturers generally require minimum orders—frequently at least $50—before they will accept an order for direct shipment. In addition, several drug manufacturers require that the buyer purchase a yearly minimum amount of drugs in order to continue as a direct purchaser. Some drug manufacturers are apparently selective in deciding which retailer can receive direct shipments, and which must purchase all products through wholesale channels. Some of the major pharmaceutical manufacturers will not sell products to community pharmacies except through wholesalers. (*34*)

Agents

The number of agents engaged in the sale of drugs decreased from 212 in 1958 to 207 in 1963 (Table 9). During the same period, their sales increased from $290 to $479 million. Slightly more than 90 percent, or 189 firms, reported sales of pharmaceutical products, although less than half of the firms provided commodity line information. Agents probably have less than seven percent of the total prescription drug wholesale market.

In terms of both numbers of firms and sales volumes, manufactuers' agents represent the leading type of agent middleman (Table 13). These are independent firms which function like and in conjunction with the marketing departments of a manufacturing firm. Since they usually do not maintain inventories, they have lower operating expenses than do merchant wholesalers or manufacturers' branch offices, averaging about 5.4 percent of sales.

Table 13

Number and Operating Expense Percentages of Agents Selling Prescription Drug Products, 1963 [a]

Type	Number of firms	Operating expenses as percent of sales
Merchandising men and brokers	18	9. 4
Commission men	23	7. 2
Manufacturers agents	116	5. 4
Selling agents	24	5. 7
Purchasing agents	8	4. 0

[a] Source: U.S. Department of Commerce; "Census of Business," U.S. Government Printing Office, Washington D.C., Vol. 4, p. 9–85.

Selling agents operate like manufacturers' agents and have similar operating expenses. They usually undertake more activities than do manufacturers' agents, and sometimes assume the entire marketing function. They generally do not make direct delivery of products, provide only limited credit, and do not provide management aids to their customers.

Agents make the larger portion of their sales to wholesalers (Table 10). Many economic authorities classify them as wholesalers' wholesalers.

Cooperative Drug Wholesalers

Cooperative drug wholesalers are merchant wholesale establishments owned by retailers. The first such organization for retail drugstores was established in Philadelphia in 1888. The *Census of Business* reports that in 1963 there were 34 cooperatives, with a total annual sales volume of $86 million. (*35*, p. 9–85)

These firms were created by the retailers in order to achieve lower prices for the products they buy. Most do not offer credit, delivery, or the services of field salesmen. The cost savings resulting from limited services and quantity purchases are usually passed on to the retailers in the form of an annual rebate based upon the quantity of products purchased during the year. In recent years, there has been a trend towards increased services which has resulted in increased product costs.

Cooperatives are also experiencing the pressures of higher operating costs and competition from the manufacturer who sells directly to retailers.

CHAPTER 12

COMMUNITY PHARMACIES

State and Federal laws require that all prescription medications must be dispensed by or under the direct supervision of a licensed practitioner of pharmacy or medicine, who must be licensed by the State in which he practices. The pharmacy from which a drug is dispensed must also be licensed by the State. It is interesting to note that the requirement to license the firm as well as the practitioner does not apply to a physician's office where drugs may be stored, nor in some States to hospital pharmacies.

Community pharmacies, often called retail or neighborhood pharmacies, are business firms licensed by boards of pharmacy to dispense drugs, under the supervision of a licensed practitioner, to members of the community. Among these are: independent pharmacies, chain drugstores, prescription pharmacies, and pharmaceutical centers.

The first two combine the professional activities of the pharmacist with the merchandising activities of a small- or large-scale retailer. This dual function performed by drugstores is a carryover of an earlier era of health care. In the 19th and early 20th centuries, it was necessary for physicians and pharmacists to locate their practices where neighborhood residents could reach them. Most pharmacists could not exist financially on the sales of prescription products alone and began to provide other retail products to their customers. Now they supplement their incomes by providing both needed health care and merchandising services which may or may not be related to health care. Chain stores have found it profitable to expand their lines of merchandise, so that today an almost endless array of products is found in these "super drugstores."

Some professional observers question whether current conditions require the pharmacist to continue his general merchandising functions.

While U.S. population, per capita consumption of drugs, and prescription prices have increased, there has been less than a 20-percent increase in the number of pharmacists in active practice during the period from 1950 to 1967. (*27*) Per capita purchases of prescriptions have increased more than four times in the period from 1940 to 1966. (*15*) Average prescription prices have increased by 247 percent during the same period. The *Lilly Digest* reports that, in 1966, prescription revenue accounted for 41 percent of the average pharmacy's sales, whereas income from prescription sales accounted for only 10.8 percent of the total in 1940. (*22*) Total community pharmacy prescription income has increased from $736 million in 1950 to $3.2 billion in 1967. (*2, 5*)

In contrast, prescription pharmacies and pharmaceutical centers rely upon prescription and over-the-counter drug product sales as their primary source of income. They do not stock toys, drug sundries, stationery, and other products found in many drugstores. Their emphasis is on the health care needs of their clients. This frequently includes dispensing drugs not commonly stocked by many pharmacies, providing fitting services for surgical garments, supplying a wide range of convalescent aids, and stocking drugs and biologicals for use by physicians.

Prescription pharmacies are those outlets in which prescription income accounts for 70 percent or more of total income. No information is available on the total number of these outlets, nor is data available on whether the number is increasing or decreasing. Some prescription pharmacies are owned by chain drugstores as a separate operation. Other prescription pharmacies have expanded the number of their outlets and can be technically classified as chain stores.

In addition to these retail institutions, which have been the traditional sources of prescription drugs, there are other firms which maintain prescription departments and sell nonprescription drug products. Included are department stores, variety stores, food stores and large discount centers. These businesses began to enter the prescription drug field after World War II, and have become an important source of drugs for some individuals.

Independent Pharmacies

Independent pharmacies are the traditional drugstores owned and operated as sole proprietorships or partnerships, or closed corporations in which the capital stock is held by a few individuals. The owners of these firms need not be pharmacists, since State laws allow a nonlicensed individual to obtain a pharmacy ownership permit. Most of the States, however, require that only a pharmacist may dispense prescriptions, so such outlets must have a licensed practitioner in charge.[a] In most cases, however, the owners themselves are pharmacists.

Number of Outlets. As might be expected, the number of independent pharmacies increased, with minor fluctuations, in the period immediately after the end of World War II, although the number did not reach that of predepression year 1922. (*32*) The *American Druggist* reported 44,001 independent pharmacies in 1950 (Table 14) and 48,218 in 1963. (*3*) However, since 1964, the number of independent pharmacies has shown a steady decline. By 1967, the number had fallen to 46,674.

Sales. In all types of independent pharmacies, major emphasis is placed upon the health care needs of the community, with only minor emphasis on the sale of nonhealth-related products. Prescription income alone accounts for about 40 percent of the total sales volume of these outlets. (*22*, p. 4) Sales of over-the-counter drugs and related drug products combined with prescription sales account for more than 65 percent of the total independent pharmacy income.

Both the total sales volume and the prescription revenue of independents have shown an annual increase since the end of World War II. The rate of increase, however, has been less for independents than for chainstores. Prescription incomes in the period 1950 to 1967 increased by 328 percent for independents and 498 percent for chains, while total sales increased 141 percent for independents and 344 percent for chains. Between 1950 and 1960, total chain store prescription income increased at a slower rate than it did for independents, but chain store prescription income increased 160 percent from 1960 to 1967, while prescription income of independents increased only 52 percent (Table 14).

The independent pharmacies still dominate the prescription market, but their share has diminished slightly, from 92.1 percent in 1950 to 89.3 percent in 1967. The independent pharmacies also had 78.6 percent of all drugstore sales in 1950, but only 66.6 percent in 1967. Thus, while sales in both chains and independents have increased, chain stores had a significantly larger portion of the total market in 1967 than in 1950, but with only a slightly greater increase in prescription revenues.

Table 14

Number of Pharmacies, Sales Volumes, Prescription Incomes, and Average Prescription Prices of Independent and Chain Outlets, for Selected Years 1950 to 1967 [a]

	1950	1960	1965	1967
Number of outlets:				
All outlets	47, 663	51, 386	52, 466	52, 265
Independents	44, 001	47, 342	47, 485	46, 674
Chains	3, 662	4, 044	4, 981	5, 591
Sales volume (millions):				
All outlets	$3, 815	$7, 427	$9, 278	$10, 862
Independents	2, 999	5, 641	6, 491	7, 235
Chains	816	1, 786	2, 787	3, 627
Rx income (millions):				
All outlets	$736	$2, 043	$2, 787	$3, 250
Independents	678	1, 910	2, 527	2, 903
Chains	58	133	260	347
Average Rx price:				
All outlets	$2. 03	$3. 22	$3. 35	$3. 49
Independents	2. 04	3. 22	3. 36	3. 50
Chains	2. 03	3. 19	3. 25	3. 42

[a] Source: American Druggist, 1951, 1961, 1966, 1968.

Costs of Operation. The 1966 issue of *Lilly Digest*, generally the major source of operating expenses data for independent pharmacies, provides "an authoritative review of community pharmacy operations based on those pharmacies that submit data to the Lilly Analysis Service." (*22*, p. 1) The *Lilly Digest* data show that operating expenses accounted for 30.9 percent of sales of the average pharmacy sales volume, while profits before taxes represented about 5 percent. (*22*, pp. 9–11)

Operating expense percentages generally show an inverse relationship to sales volume. Pharmacies reporting annual sales volumes of less than $40,000 showed an average expense of 37.2 percent of sales, with a 1.9 percent net profit. Pharmacies with annual sales of more than $400,000 reported average operating expenses of 30.3 percent of sales and profits of 4.3 percent. (*22*, pp. 9–11) The lowest average operating expense percentage was reported by outlets with annual sales volumes between $225,000 and $250,000. For these pharmacies, the average profit before taxes was 5.1 percent of sales. There was not, however, a great variation in average operating expense percentages for pharmacies with annual sales volumes of $80,000 or more; these ranged from 29.6 to 32 percent of sales (*22*, pp. 9–11)

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[a] For a discussion of exceptions to this ruling, see the section on State pharmacy laws, pp. 77–82.

As annual sales volumes increase, operating expense dollar expenditures also increase, ranging from an average annual expenditure of $11,620 for pharmacies with an annual volume of less than $40,000, to $162,761 for those with a volume more than $400,000.

The *Lilly Digest* also reports that as a greater percentage of a pharmacy's sales is derived from prescription income, operating expense percentages increase. Stores in which prescription income accounts for less than 15 percent of total sales volume had an operating expense of less than 28 percent, whereas those with prescription income over 75 percent of sales reported an operating expense of 34.4 percent. (*22*, pp. 16–17)

There is only a slight geographic variation in operating expenses both in terms of dollars and in terms of percentage of sales. (*22*, pp. 46–47) Pharmacies on the Pacific Coast reported the highest dollar and percentage figures for expenses, which were related primarily to higher salary and rent expenditures. The highest net profit, both in dollars and in percentage of sales, was reported in the East South Central States (Mississippi, Alabama, Tennessee, and Kentucky).

Average annual operating expenses increased from $16,000 in 1946 to $53,923 in 1966, with an annual sales volume increase from $69,000 to $175,000 (Figure 13). The *Lilly Digest* reported that average total expenses took 24 percent of the sales dollar in 1946; by 1967, expenses had increased to 32 percent (Figure 14). Average annual net profits increased from $5,000 in 1946 to $10,000 in 1966; however, net profit as a percentage of sales fell from a high of 8.6 in 1946 to 4.8 in 1966. Salaries have shown less than a $1,000 average annual increase during the 20-year period, and consume a slightly larger portion of the sales dollar (Figure 15).

While the average annual sales volume increased 152 percent, profits increased 80 percent.

Capital Investments. According to *Lilly Digest* data, the average total of assets for pharmacies was $66,430 in 1966, up 4.4 percent from 1965, and reached an all-time high in 1966, with inventory accounting for more than half of total assets. (*22*, pp. 54–58)

As sales volume increases, the value of total assets also increases but at a slower rate. Pharmacies with annual sales volume greater than $200,000 however, have more than three times the investment in inventory than do those with sales volume under $100,000. Stores with annual sales of more than $400,000 have less than three times the inventory investments in prescription products than do stores with an annual volume of less than $90,000, but they have more than six times the investment in other products. (*22*, pp. 10–11)

Sales per dollar invested in prescription products, as well as other merchandise, apparently increase as the total sales volume increases.

Data on the relationship of profits to capital investments in pharmacies are also limited. The *Lilly Digest*, however, reports an average return on net worth of 21.1 percent, with a smaller return for pharmacies with low sales volume, and less for older than for new pharmacies. (*22*, pp. 60–61) The smaller return on investments for older pharmacies probably results from an increase in the proportion of owner's capital to liabilities as the pharmacy matures. In other words, it is more a factor of liquidity than one of lower dollar profits. Generally, new pharmacies rely heavily on liabilities as a means of financing. This fact is borne out by the return on total assets, which is 12.8 percent for new outlets as compared to 12.2 percent for older pharmacies.

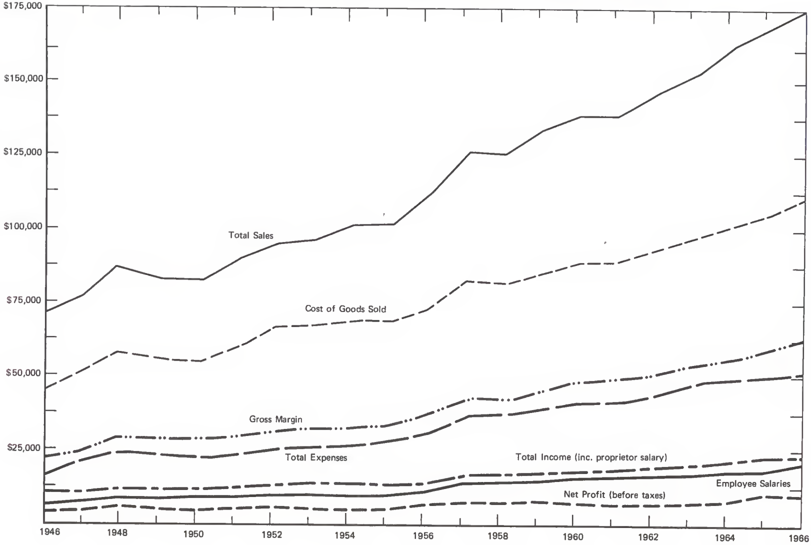
Return on investment is also dependent upon the rate of stock turnover. Higher stock turnover rates can result in lower investments in inventories, resulting in greater returns on investments.

Pricing Practices. Most community pharmacists apply the same pricing systems to both drug and nondrug products by adding a percentage of the wholesale cost. This system is termed the percentage markup, or margin system. Not all products in the pharmacy are marked up by the same percentage; however, the average markup for all items is generally believed to be about 50 percent of the acquisition (wholesale) cost, with prescription drugs usually marked up by 65 to 100 percent.

As noted elsewhere, a detailed study of nearly 200 million prescriptions purchased by the elderly in 1966 showed an average cost at the retail level of $3.91. (*36*) Based on published wholesale prices, the average acquisition cost was $2.10, indicating a markup of 86.2 percent. Since the actual acquisition cost was probably lower, at least in some instances, because of discounts or rebates, the average markup may have been significantly higher than 86.2 percent.

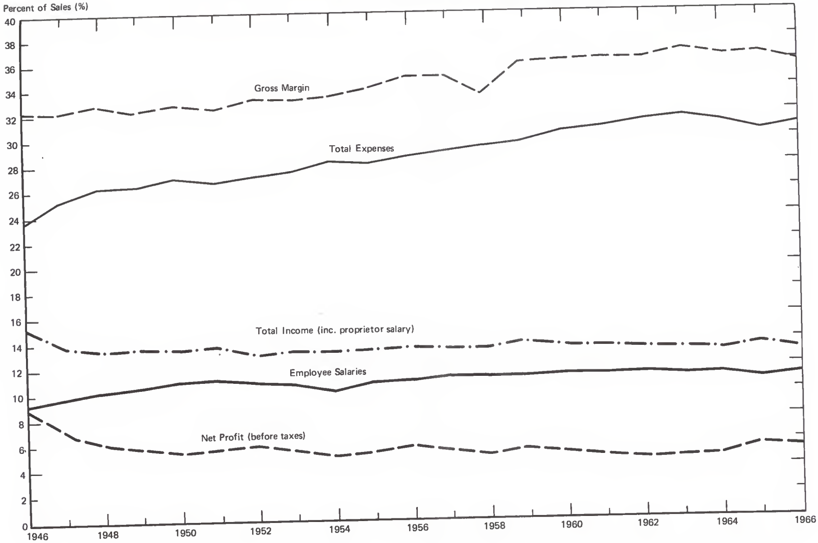
The pricing of prescriptions has been under review by pharmacists since about 1953. The American Pharmaceutical Association and other groups advocate the use of a flat dispensing fee added to the wholesale cost of each prescription in place of the usual percentage markup. The National Association of Retail Druggists has opposed the use

Figure 13.—Average Sales, Expenses and Profits, Community Pharmacists, 1946–1966



SOURCE: ELI LILLY AND COMPANY, LILLY DIGEST SURVEYS, 1946–1966, INDIANAPOLIS, IND.

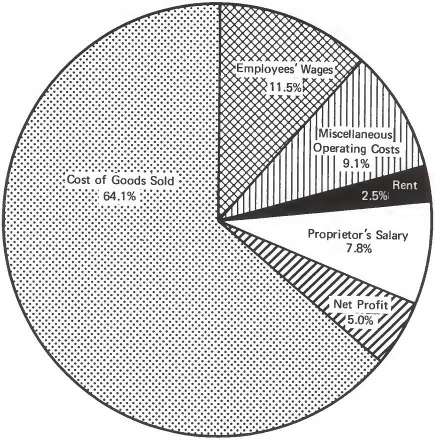
Figure 14.—Summary of Pharmacy Operations as Percent of Sales, 1946–1966



AVERAGE PHARMACY TOTAL SALES:
1946 – $69,422
1951 – $89,756
1956 – $111,845
1961 – $139,176
1966 – $174,646

SOURCE: ELI LILLY & CO., LILLY DIGEST SURVEYS, 1946–1966, INDIANAPOLIS, IND.

Figure 15.—Distribution of the Pharmacy Prescription Dollar, 1966



SOURCE: ELI LILLY & CO., LILLY DIGEST SURVEYS, 1966, p. 8, INDIANAPOLIS, IND.

of the fee and advocated that pharmacists stay with the traditional system. Some pharmacists are already changing to the fee system, but how rapidly is unknown.

According to one author, the primary difference between the two systems is that of philosophy. The traditional system uses a commodity approach, he says, while the fee system uses a service approach.

> "The application of [the traditional system] in the hands of many pharmacists has been largely arbitrary and certainly empirical. Often a rule-of-thumb guide line has been followed, such as 'double all costs,' except in cases that require special handling; for example, narcotic-containing prescriptions, where an additional 25 to 50 cents was added.
>
> "The reason that application of this system was essentially arbitrary is twofold. First, the pharmacist, all too often, did not know what his operating expenses were. Second, the pharmacist did not have any particular philosophy concerning the act of dispensing prescriptions. Other items that he distributed were 'sold' in the customary retail channels by 'marking up the basic cost' by an appropriate amount. In other words, the manner and environment of pharmacy practice dominated both the philosophy and procedure for charging the public for prescription medication.
>
> "During this period, the pharmacist had little or no concept of pharmaceutical service beyond the physical act he performed in providing a distributive function.
>
> "Throughout these years, the commodity aspect of the prescription was the center of the pharmacist's attention. He received a personally executed order from the physician and, after assembling the specified ingredients, dispensed them to the patient . . . . He was a middleman,

> performing by law acts of distribution of medicinal agents from one point in society to another—the latter being occupied by the patient. His professional function, as he saw it, was one of distribution.
>
> "One of the basic defects of the markup system lies in the fact that the patient's cost is related only to the wholesale cost of ingredient, when in reality the cost of providing prescription service does not vary with this cost." (*11*)

The services rendered by the pharmacist are not, however, a function of the cost of the drug product. In most instances, he performs the same services no matter whether the medication costs 10 cents or 10 dollars.

The markup system appears to lay a heavy burden upon the individual unfortunate enough to require expensive medication. Adding a percentage to the wholesale cost of low-priced medications results in a net loss to the pharmacist and a net gain to the patient who has purchased his medication below cost, but this loss is made up when a more expensive medication is dispensed. In the latter case, the percentage markup brings in more than enough to cover all expenses. Patients who must buy more expensive medications actually subsidize those who obtain lower cost prescriptions. If the pharmacist is correct in adopting the markup percentage, he will make an overall profit by this system, since the losses will be more than covered by the gains.

The dispensing fee approach suggests that a flat amount to cover all costs of dispensing each prescription be added to the ingredient costs.

> "In applying the fee concept to a pharmacy practice, a pharmacist makes two assumptions which are the philosophic principles underlying its use. First, the pharmacist is a health specialist by virtue of his knowledge, education, and training, and dispensing prescription medication is a pharmaceutical service. For this act, he receives a fee. . . . Second, the service a pharmacist provides in dispensing prescriptions is, in general, the same for all prescriptions, and the cost of providing this service remains relatively constant from one prescription to the next." (*11*)

The use of the dispensing fee reduces the costs of high-priced medications while increasing the costs of low-priced drugs, and certain patients would find that their drug costs had increased. The system is more equitable, however, because it eliminates subsidization of some patients by others.

The dispensing fee concept has not received universal acceptance, although many pharmacists have adopted it. One author believes that this results primarily from the fear of change. (*14*)

There is some fear that the use of the dispensing fee will greatly increase the total costs to long-term users of low-cost medications, who under the markup system would normally receive prescriptions below the actual dispensing cost. These patients may be properly served in appropriately selected cases if physicians can be induced to prescribe in larger quantities; thus the patient would pay one dispensing fee for a medication which would last several months, instead of several dispensing fees for smaller quantities of the medication prescribed a number of times.

Many pharmacists, apparently unable to make a complete change from one system to another, use a combination of both the flat fee plus a percentage markup. This has the advantage of reducing somewhat the cost of high-priced medications and at the same time allowing the pharmacist to cling to traditional pricing methods.

Chain Drugstores

While there is not complete agreement, the usual definition of a chain drugstore includes the following characteristics:

- The outlets are all centrally owned.
- The outlets are managed from central offices to give continuity and homogeneity to their operations.
- There are four or more outlets dealing with similar products and operating under a common name.

Some marketing experts argue that a chain must be composed of four or more outlets, while others feel that the number of outlets is not important. All agree, nevertheless, that chains have centralized decision-making for all outlets, as opposed to a decentralized decision-making system which can exist even where there are two or three outlets under a single ownership. In order to conform with Bureau of Census and National Association of Chain Drug Stores criteria, a chain is defined here as having four or more outlets.

Historical Development. Chain drugstores represent a relatively recent development. Although some chain outlets existed in the early 1900's, their greatest growth and development came in the period immediately following World War I. Indeed, the period 1918 to 1929 is termed the "chain-store age" by marketing authorities.

Like all retail institutions, chain stores developed to meet socio-economic needs. Rising prices, coupled with a period of relative scarcity of products, sent people looking for bargains in foods, drugs, and sundry items. Through a series of policies and practices, chain drugstores were able to meet the needs of some of these people. They offered their customers lower prices which resulted from (1) a policy of increased volume at lower margins, which gave them higher dollar profits; (2) large quantity purchases, which reduced the invoice cost of the products; (3) reduced retail services, such as not offering credit or deliveries; and (4) a specialized management which presumably could make decisions more effectively in all phases of retail operations. While the independent must make all decisions for his firm, a chain can select individuals highly skilled in each phase of management.

Chain drugstore growth began to level out in 1929 and remained relatively constant until the past few years. The end of the rapid growth of the chain store age resulted from several factors: (1) the enactment of Fair Trade laws and the Robinson-Patman Act, which nullified some of the economic advantages of chain stores; (2) discriminatory State taxes which were placed upon chain stores; (3) internal inefficiencies which eventually occur in large firms; and (4) the improvements in management by independents who had not been forced out of business by the chain drugstore competition.

Chain drugstores appear now to be in a new era of growth. Since 1950, they have experienced a yearly increase in total sales volume and prescription income (Table 7). From 1955 through 1967, they have also shown a yearly increase in the number of outlets, while independents, as already noted, have shown a decline in the number of outlets in the last four years. One explanation for the increases in the relative number of chain drugstores is that a three-store independent owner who opens a fourth outlet "brings about an increase of four chain drugstores, and a decrease of three independents." (*21*)

Costs of Operation. Unfortunately, only incomplete data are available on chain drugstore operations. The *American Druggist*, however, conducts an annual study of drug chain financial reports which provides some useful information.

As a percentage of sales, chain store operating expenses have declined annually since 1960, although the dollar amount has increased. Net profit increased from 1.8 percent of sales in 1962 to a high of 5.1 percent in 1966. Chain stores showed, nevertheless, a reduced net profit percentage in 1967 although the dollar volume increased. This decline was largely the result of "price cutting required to meet discount competition and because of increased operation expenses, mostly involving wages." (*6*).

Average operating expense percentages for chain drugstores are slightly less than those for independents with annual sales volumes of greater than $400,000, while profit percentages are slightly higher for chains than for independents. Long range trends in operating expenses and profits show a movement similar to that in independent pharmacies. No information is available on prescription chains nor on prescription department operating expenses and investments. Capital investment data for some chains are available from financial reports, but apparently no study has been made to determine the average per outlet.

Pricing Systems. Chain drugstores use the same pricing systems as do independents. Their approach to prescription pricing is also similar to that of independents. One study indicates that chains have not adopted the dispensing fee concept in prescription pricing, but several have adopted the fee plus percentage markup. (*13*) A more recent study, conducted by the National Association of Chain Drug Stores, showed that 75 percent of chain drugstores favored the use of a fee for government-sponsored drug programs. (*28*) About two-thirds of those favoring the use of a fee wanted a fixed-fee policy while one-third wanted a flexible markup that would change as the acquisition cost changed.

Chain drugstores buy much of their prescription products directly from the manufacturers for distribution through their own warehouses. The invoice cost per unit of products purchased directly from the manufacturers is less than the cost per unit purchased through wholesalers. But chains incur additional costs in direct purchasing; they must assume some of the transportation costs, some storage costs, and some processing costs as well as other expenses which must be taken into consideration when determining actual acquisition costs. These additional costs account for the similarity in gross margins between chains and independents.

Various studies indicate that chain store prescription prices are slightly lower, on the average, than those of independents (Table 14). This does not necessarily mean that chain store prices on all drugs are lower. It may mean that chain prices for some prescription products are appreciably lower than independents, about the same for others, and higher for some. This price variation may also result from an actual difference in the types of prescriptions dispensed. For example, chains may dispense more drugs for chronic disease and less for acute conditions, whereas independents may dispense more for acute illness and less for chronic conditions.

Prescription Pharmacies

Prescription pharmacies are considered to be community pharmacies which derive 70 percent or more of their income from dispensing prescriptions. They place major emphasis on the health care of the community and little or no emphasis on general merchandising functions. In general, prescription pharmacies occupy less physical space than do other outlets, but may achieve income as high as many of the independent or chain drugstores.

No information on their number is available. Most are established near physicians' offices, some in medical office buildings, others in clinic buildings, and still others in structures adjacent to medical office buildings or clinics. In some of the larger medical buildings, more than one pharmacy may be found. This type of pharmacy may have direct telephone lines into the office of physicians in the area who can obtain drug information and relay prescription orders for their patients.

Prescription pharmacies may be classified as independent pharmacies in that most are owned and managed by solo entrepreneurs. Other prescription pharmacies are owned by chain drugstores and usually operate under a name different from that of the parent organization. Still others are multiple-unit or chain outlets owned by one organization.

Costs of Operation. The gross margin and total expense percentages of prescription pharmacies are higher than those of independents and chains, while the net profit percentage is slightly lower (Figure 16). Their costs for rent, deliveries, and telephone as a percentage of sales are higher than for other pharmacies. (*22*, p. 21) Like all other drug outlets, however, increased cost of goods sold and rising operating expenses appear to have reduced profits for prescription pharmacies. (*22*, p. 23)

Capital Investments. The capital investment necessary to operate a prescription pharmacy appears to be less than that needed for other types. Pharmacies with prescription income accounting for 60 to 75 percent of total income reported an average total inventory of about $17,500, with only $7,000 in nonprescription products. (*22*, p. 22) Pharmacies reporting prescription incomes at more than 75 percent of total income had only an average $13,000 investment in inventory, $11,000 of which was for prescription products. The average independent community pharmacy had a total inventory investment of $30,000, with only $10,000 invested in prescription drug products.

Pricing Systems. Prescription pharmacies use the same pricing systems as do independent pharmacies and chain drugstores, but there is some indication that prescription shops are more likely to use the flat dispensing fee rather than the percentage markup. The American College of Apothecaries, a professional society of pharmacists owning or practicing in prescription pharmacies, was the first group to advocate use of a dispensing fee.

Pharmaceutical Centers

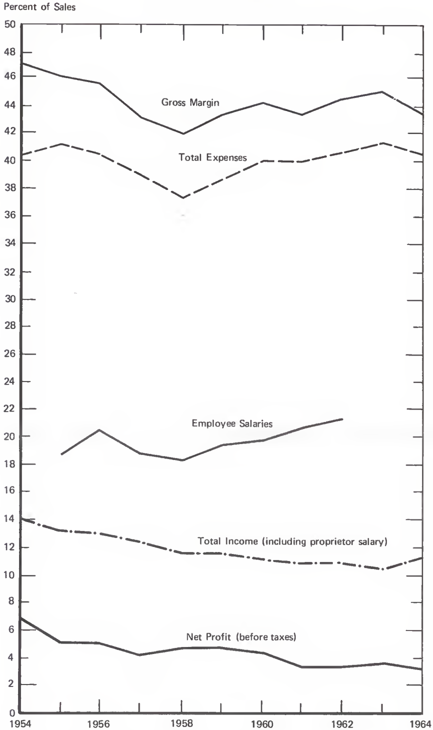
The concept of a pharmaceutical center as a special type of pharmacy was formally introduced in 1965 at the annual meeting of the American Pharmaceutical Association, although certain aspects were already in effect. The centers represent a refinement of the independent pharmacy directed toward patient care, and are closely related to prescription pharmacies, but place even greater emphasis upon the professional activities of the pharmacist. There are approximately 200 pharmaceutical centers recognized as meeting the standards adopted by the American Pharmaceutical Association (*10*)

Among the criteria needed to meet the American Pharmaceutical Association standards are these:

- The pharmacist must have personal contact with the patient when each prescription order is presented.

- The directions for use of each drug must be discussed, along with information on possible

Figure 16.—Summary of Prescription Pharmacy Operations as Percent of Sales, 1954–1964



* NOTE These are pharmacies specializing in Rx service; due to their unique characteristics, the figures differ from those found in a survey of all pharmacies

SOURCE: AMERICAN COLLEGE OF APOTHECARIES, OPERATING COSTS OF PRESCRIPTION PHARMACIES, 1958–1964, WASHINGTON, D.C.

side-effects, physiological changes that may result, and any other pertinent aspects of drug therapy.

- The pharmacy must maintain patient records which contain data on drugs dispensed to each patient, along with the usual information on age, sex, drug allergies, etc.
- No prescription may be dispensed or over-the-counter items sold until the patient's record has been consulted to check on possible allergic responses, adverse drug reactions, or drug contraindications.
- The fixed dispensing fee must be used by the centers for all prescriptions dispensed.
- The center must serve as a Public Health Information Center for distribution of health care literature, and it must provide a reference library and consulting area for use by pharmacists and physicians.
- All products are sold directly by or under close supervision of the pharmacists. (*10*)

The center is more than a physical establishment. It is a concept in which the pharmacist reorients his activities from being a distributor of drugs to serving as an active participant in the total health care of the community. Rather than being distributor-oriented, the pharmacist becomes patient-oriented in a community environment.

Other Retail Drug Vendors

Prescription departments, under the supervision of pharmacists, can be found today in about 1,250 department, food, variety, and discount stores. These non-drugstore outlets have experienced continued increases in their prescription sales, which were $292.6 million in 1967, up from $226.6 million in 1966 (Table 15).

Table 15

Number of Prescriptions Filled and Prescription Income for Non-Drugstore Outlets, 1965–1967 [a]

	1965	1966	1967
Total number of prescriptions (millions)	50. 3	72. 9	91. 1
Total prescription income (millions)	$149. 0	$226. 6	$292. 6
Average prescription price	$2. 96	$3. 11	$3. 21

[a] Source: *Drug Topics*, March 4, 1968 and March 20, 1967.

In 1967, these outlets dispensed a total of 91.1 million prescriptions at an average prescription price of $3.21. (*21*) In 1966 the average prescription cost was $3.11, and 72.9 million prescriptions were dispensed. The 1966–1967 average prescription price increase was greater for non-drugstore outlets than for chain drugstores or independent pharmacies.

Pharmacy departments located in these outlets must be licensed by the State as are any other retail pharmacies. Some State boards of pharmacy, however, have been reluctant to license such outlets, although they have usually been forced to do so by court action.

The pharmacy departments in these establishments must be under the management of a pharmacist, but some outlets—especially the discount stores—have frequently experimented with the use of supervised non-pharmacist personnel to aid in the filling of prescriptions. Data are not available to evaluate the effectiveness of such aids in terms of efficiency and patient care.

No data are available on pricing systems, operating expenses, or capital investments in these outlets.

CHAPTER 13

HOSPITAL PHARMACIES

Hospitals have traditionally provided medical care for inpatients, emergency care for outpatients and—in certain governmental and teaching institutions—preventive, diagnostic and therapeutic care for indigent outpatients. Today, hospitals are rapidly becoming community health centers, providing the general public with outpatient diagnostic services, clinics, and staff offices, often housed in one health center complex. (*16*, p. 7)

Many hospitals now provide outpatient prescription services through the hospital pharmacy. A thorough study of this practice and the effect on the pharmacy profession as a whole, and particularly on the community pharmacy, was reported in 1966 by the Commission on Pharmaceutical Services to Ambulant Patients by Hospitals and Related Facilities. The Commission was sponsored by the American Pharmaceutical Association and the American Society of Hospital Pharmacists, with representatives of the American Hospital Association and the American Medical Association also serving as members. (*12*)

When providing outpatient services, hospital pharmacies compete with other community pharmacies and other vendors for the community prescription drug dollar. Only about two-thirds of the hospitals with 200 beds or more have some outpatient pharmacy services although more than 99 percent have inpatient pharmacy services. (*16*, p. 117)

Hospitals involved in outpatient activities may be either nonprofit or profit-making proprietary organizations. Nonprofit hospitals, of course, operate on a tax-free basis; however, recent Internal Revenue Service regulations require the payment of taxes for any nonrelated business income such as that derived from the operation of a pharmacy in a hospital-owned physicians' office building. Some community hospitals are actually tax-supported institutions provided by city or county governments. Proprietary hospitals are reported to account for about 4.4 percent of all hospital drug purchases, while nongovernment-owned voluntary hospitals purchase 52.8 percent (Table 16).

A large number of hospitals apparently do not employ full-time hospital pharmacists, although there are wide discrepancies in the data. *American Druggist* (*4*) reports that only 59.5 percent of all hospitals had pharmacies (Table 17). As of June 1, 1967, 6,973 hospitals had been certified by the Division of Medical Care Administration and the U.S. Public Health Service to give patient care

Table 16

Hospital Purchases of Drugs by Type of Ownership, 1967 [a]

Type of hospital ownership	Drug purchases	Percent of total hospital drug purchases
Federal	$103, 717, 700	12. 7
State and local Government	245, 643, 200	30. 1
Proprietary	35, 611, 700	4. 4
Voluntary	430, 754, 400	52. 8
Total	$815, 727, 000	100. 0

[a] Source: Modern Medicine Publications: "Medical Market Guide," 1967, p. 43.

Table 17

Number of Hospital Outpatient Prescriptions for Selected Years, 1962 to 1965 [a]

	1962	1964	1965
Number of hospitals	6, 970	7, 238	7, 252
Number of pharmacies	3, 670	4, 061	4, 138
Percent with pharmacies	52. 6	56. 1	59. 5
Outpatient prescriptions:			
Government	31, 458, 000	40, 458, 000	46, 406, 000
Nongovernment	21, 742, 000	29, 084, 000	34, 549, 000
Total	53, 200, 000	69, 542, 000	80, 957, 000
Percent of all outpatient prescriptions [b]	7. 0	8. 2	8. 9

[a] Source: American Druggist, New York, June 6, 1966, p. 12.

[b] Does not include prescriptions dispensed from prescription departments of food, department or discount stores.

under Medicare. Presumably, this means that 6,973 hospitals had the services of a pharmacist available. On the other hand, the National Association of Boards of Pharmacy reported that on January 1, 1967, there were only 2,821 hospital pharmacies employing 6,734 pharmacists. (*27*)

All community pharmacies must be under the immediate supervision of a pharmacist, but this protection to the consumer is not necessarily given to large numbers of hospital inpatients. In some areas, hospital pharmacies are less subject to control and inspection by boards of pharmacy than are community pharmacies:

- Only 30 States give boards of pharmacy authority over hospital pharmacies, while six States give joint authority to boards of pharmacy and boards of health.

- Pharmacy permits are required of hospital pharmacies in only ten States.

- In only five States, hospital pharmacies are specifically required to comply with State pharmacy laws.

Why hospital pharmacies—particularly those with outpatient services—do not have to comply with the same regulations as do community pharmacies is a question yet to be answered.

In 1965, hospitals dispensed 8.9 percent of all outpatient prescriptions, up from 7.0 percent in 1962.(*4*) In 1957, about 50 percent of the outpatient prescriptions were dispensed to indigent or near indigent patients. (*16*, p. 118) Private patients, on the other hand, received only 32 percent of the outpatient prescriptions. The rest were dispensed to "others," which included recipients of medical care under comprehensive health plans, military dependents, etc. Thus, 10 years ago, about 70 percent of these prescriptions were either partially or fully subsidized. Current data are not available.

Costs of Operation. Data on hospital pharmacy operating costs are not generally made public.

Traditionally, hospitals have used the pharmacy as a profit-making department, using the profits to subsidize other hospital services. One hospital pharmacy has reported an average outpatient prescription price of $3.75. The average acquisition cost was $1.90 and dispensing costs were $0.59, giving a *net* profit of $1.26. (*33*)

The average outpatient prescription price in hospitals probably approximates the national community pharmacy average prescription price, even though drug costs and operating expenses may be appreciably lower, and no income taxes may be involved. Although individual hospitals have sought to justify the profits from such income-producing departments, the American Hospital Association has for years had a policy stating that changes should be based on the costs of the departments providing the services rather than on the general budget needs of the hospital. (*7*, *19*)

Subsequently, Medicare regulations have prohibited payment for profits of this type for drugs dispensed to the aged hospital *inpatient*, and payment may be made to cover only the actual total prescription costs. What effect, if any, this has had on drug costs to other hospital inpatients and to both the aged and other outpatients has not been determined.

Pricing Systems. Hospital pharmacies use pricing systems similar to those used by other pharmacies. Some outlets use the percentage markup system, while others use fixed dispensing fee systems. A shift to the fee system has been noted in recent years.

CHAPTER 14

MAIL ORDER PHARMACIES

The concept of providing prescription drugs by means of mail orders is of relatively recent origin. Available data indicate the existence of at least seven such outlets. The United Mine Workers of America maintains a mail order program for chronically ill retired union members. (*37*, p. 27)

Some of these pharmacies cater to the elder drug users with chronic conditions who must find a low-cost source for drugs because of limited funds. Other customers appear to be individuals located in areas where no pharmacies exist.

Limitations. Mail order pharmacies have not expanded as rapidly as expected. They are specifically forbidden in 11 States and specifically allowed in only one. State boards of pharmacy apparently disapprove mail order practices because the boards have no supervision over the outlets or the practitioners and feel that they cannot carry out their responsibilities to the public.

Federal regulations also restrict the operations of mail order pharmacies by prohibiting the use of the mails for narcotic drugs.

Finally, the time lag—from the moment a physician writes a prescription order to the time at which the patient receives the medication—generally limits the use of mail order pharmacies to patients receiving drugs for chronic conditions. A patient with an infection requiring the immediate use of antibiotics, for example, cannot wait four or five days to receive the drug, while a patient in constant need of a drug for hypertension can plan ahead and obtain the needed medication before he exhausts his current supply.

Cost of Operation. No data are available on the operating costs of mail order pharmacies. For an outlet serving two groups (*1*, *29*), it is known that mail order prescription services are limited to the 800,000 members of the organization, and the facility currently dispenses 4,000 prescriptions daily through the mails. Thirty-five full-time pharmacists are employed in a near-production line operation, with one pharmacist reviewing each prescription, a second filling the order, and a nonpharmacist typing the labels. If problems or questions arise in the prescription review, a pharmacist consults with the prescribing physician by telephone. Dual prescriptions for one patient are reviewed for compatibility, but patient records are not maintained to check on drug allergies or drug incompatibilities. In this respect, however, this particular pharmacy does not differ from most other drug distributors.

Mass purchasing, minimal overhead, and a tax-free status allow it to dispense medications at an estimated 25 percent savings to the patient, but this outlet has indicated it will shut its doors if outpatient drug benefits are added to Medicare. It has stated that its sole purpose has been to provide low-cost, quality drugs to retired persons.

CHAPTER 15

DISPENSING PHYSICIANS

Dispensing physicians are those who stock a more-or-less complete line of drug products, selling medications directly instead of writing prescriptions for patients to have filled at community pharmacies.

Drug supplies are obtained directly from a manufacturer or a wholesaler, and what the physician charges may be the same as the prices set by pharmacies in his community—or substantially higher or lower.

The number of physicians who retail drugs to their patients is difficult to determine. It has been estimated that 23 percent of all physicians were dispensing drugs directly to more than 50 percent of their patients in 1947 (*25*) that the proportion of such doctors had dropped to 16 percent in 1950, and that only 10 percent of all patients purchased drugs from physicians in 1967. (*24*)

Some physicians find it necessary to sell drugs directly to their patients because they practice in isolated areas in which no pharmacy is available. This situation, however, is becoming increasingly rare because of rapid means of transportation between even outlying areas and population centers.

Physician-dispensing has been the subject of some controversy between pharmacists and medical groups, and even within medical organizations.

The American Pharmaceutical Association and the National Association of Retail Druggists have opposed the concept of dispensing by physicians—except in emergencies and in geographical situations which make it essential. Some local medical societies have also opposed this practice.

On the other hand, the American Medical Association has decided that it is not unethical for a physician to dispense so long as the patient is not exploited. (*9*) The AMA is thus in the position of insisting that the patient must have free choice of physician, but need not have free choice of pharmacist.

CHAPTER 16

PHYSICIAN-OWNED PHARMACIES

In 1964, according to the National Association of Retail Druggists, there were at least 2,200 physician-owned pharmacies. The number was reportedly increasing at the rate of about 15 percent per year (*20*), with 125 in Texas, 95 in California, 45 in Illinois, and 33 in Louisiana. Based on statements of ownership filed with State boards of pharmacy, these figures do not include the numbers of physician-owned pharmacies which are listed as being owned by a corporation or a relative.

The relative advantages and disadvantages of such establishments are a matter of considerable dispute.

Physician-owned pharmacies have, at least in theory, several advantageous characteristics:

—They offer convenience to patients, since many are located in medical buildings which also house many of the physicians who send their patients to them.

—They can often purchase drugs from manufacturers or wholesalers at prices which are not available to many community pharmacists.

—They can maintain small inventories, since they need stock only those drugs prescribed by a relatively small number of physicians.

—It has been held that a physician-owned pharmacy is more likely than a community pharmacy to ensure that the patient will receive the proper medication.

Although low inventories and relatively low acquisition costs could result in lower drug prices to patients, there is no evidence that the average prescription prices set by physician-owned pharmacies are any lower than those set by other pharmacies in the community. Further, there is no evidence that physician-owned pharmacies are any more or less likely to dispense improper medication.

In contrast, there are evident disadvantages:

—Patients treated by a physician who both prescribes drugs and has a financial interest in the pharmacy which dispenses the drugs are clearly a captive audience, with no freedom of choice on where they will have their prescriptions filled.

—With the physician occupying a dual role as prescriber and dispenser, there is an obvious conflict of interest, with an evident risk of excessive prescribing.

—A physician-dominated pharmacist may not exercise needed objective review of what may appear to him to be prescription errors.

The ethical problems involved here have proved to be troublesome to the American Medical Association. (*20*, p. 193) In 1964, the AMA seriously questioned the ethical status of physician-owned pharmacies, but reversed its stand the following year. The Association currently views physician-ownership as ethical if there is no patient "exploitation."

The AMA has not set any guidelines to determine such exploitation.

CHAPTER 17

PHYSICIAN-OWNED REPACKAGING COMPANIES

A drug-repackaging company is one which purchases a drug product from a manufacturer, usually at relatively low prices, and then repackages it under its own label—at its own price.

If such a firm is controlled by one or more physicians who set the price at an extraordinarily high level, and who then prescribe its products under the repackaging company brand name—thus requiring the pharmacist to dispense it—the profits to the company and its physician-owners can be extraordinarily rewarding.

For example, it was shown that one physician-owned repackaging firm sold dextro-amphetamine sulfate under its own name for $11.30 a thousand, while another firm sold it for 85 cents a thousand. Both companies purchased the identical product from the same supplier. (*18*)

In 1965, it was reported that there were at least 140 such companies in existence in 30 States, involving some 5,000 physicians. (*18*) A Congressional report observed that "perhaps five percent of American physicians own stock in drug repackaging firms." (*38*)

The conflict of interest and the potential exploitation of patients are so apparent here that the American Medical Association, through a resolution adopted by its Judicial Council in 1967, flatly declared this situation to be unacceptable:

> "It is unethical for a physician to be influenced in the prescribing of drugs or devices by his direct financial interest in a pharmaceutical firm or other suppliers. It is immaterial whether the firm manufactures or repackages the products involved. It is unethical for a physician to own stock or have a direct or indirect financial interest in a firm that uses its relationship with physician-stockholders as a means of inducing or influencing them to prescribe the firm's products. Practicing physicians should divest themselves of any financial interest in firms that use this form of sales promotion. Reputable firms rely on quality and efficacy to sell their products under competitive circumstances, and not upon appeal to physicians with financial involvements which might influence them in their prescribing.
>
> "Prescribing for patients involves more than the designation of drugs or devices which are most likely to prove efficacious in the treatment of a patient. The physician has an ethical responsibility to asure that high quality products will be dispensed to his patient. Obviously, the benefits of the physician's skill are diminished if the patient receives drugs or devices of inferior quality. Inasmuch as the physician should also be mindful of the cost to his patients of drugs or devices he prescribes, he may properly discuss with patients both quality and cost." (*8*)

Since drugs marketed by physician-owned repackaging companies are generally available from their original manufacturers at lower cost, there appear to be no valid reasons for accepting them under any Federal drug program.

CHAPTER 18

PHARMACY LAWS AND REGULATIONS

A wide variety of State and Federal laws are currently in effect, and could presumably influence any Federal drug program developed for the elderly. Whether these laws are designed primarily to protect the patient, or to protect the pharmacist from competition—fair or unfair—is not altogether clear.

The wide divergence in the laws and regulations may be indicated by the fact that Alaska and the District of Columbia have no legal rules or regulations concerning pharmacy operations; Alaska, Hawaii, Montana, New Mexico, Tennessee, Vermont, and Wyoming have no codes of ethics in this field; several States have adopted the Code of Ethics of the American Pharmaceutical Association; and other States have their own codes which differ markedly one from the other. It must be pointed out, however, that a difference in legal status exists in many States among codes of ethics, laws, and rules and regulations. Some Boards of Pharmacy have legal control through codes, rules, and regulations by virtue of enabling legislation enacted by the various State legislatures.

Qualifications of the Pharmacist

In all States, it is necessary for a pharmacist to be a graduate of a school of pharmacy approved by the State Board of Pharmacy. Other requirements are less consistent—

- —All States but Hawaii require the applicant to be 21 years of age or older.
- —In 35 of the 50 States, United States citizenship is essential. In the remaining States, it is not specifically mentioned in the rules and regulations, laws or codes of ethics.
- —In 44 States of the 50, pharmacists are required to be of good moral character. In a few States, the owners of the pharmacies—even though not registered pharmacists themselves—must be of good character.
- —In order to simplify reciprocity, the National Association of Boards of Pharmacy has suggested that there be a standard internship, including one year of experience, three months of which are obtained after graduation. Indiana, New York, and Texas, however, require only six months of experience; Delaware requires almost two years; while Alaska, Rhode Island and Mississippi demand none. Among the other States, most of which call for one year of practical internship, some require that this training must be obtained after the first year of professional education, some require it after the second year, some require it after the third, and two require it after graduation. Nebraska requires pharmacy experience before the applicant begins his formal pharmacy education.
- —All States but Mississippi insist that graduating pharmacists pass an examination administered by their respective State Board of Pharmacy. (In actual practice, almost all Mississippi graduates take such an examination in any case, in order to fulfill reciprocity requirements.)
- —Basic requirements for reciprocity are essentially the same in most States, with the regulations insisting that the individual must have been eligible for registration as a pharmacist in the State in which he is applying for a reciprocal license at the time he received his license in his home State. California, Florida, and Hawaii, however, do not have such reciprocity agreements.
- —In Florida and Kansas, a pharmacist cannot renew his license unless he can prove he has undergone a specified amount of continuing education.
- —In Texas and Arizona, a pharmacist is required to take a loyalty oath.
- —In Texas, a pharmacist must be able to type at least 30 words per minute.

While some modern pharmacy graduates have had five or six years of college training, health manpower studies have shown that between 25 and 30 percent of all licensed graduate pharmacists have had only three years of college education—or less. (*27*)

Qualifications of Other Licensed Personnel

Assistant Pharmacists. Licenses for such individuals are no longer being issued, but some 2,300 of them—about 1,500 in active practice—are still on the roster in 28 States.

In Colorado, Illinois, Oklahoma, West Virginia, and Wisconsin, registered assistant pharmacists may operate pharmacies in towns with a population of 500 or less. In Tennessee, they may operate their own stores and fill prescriptions that do not require weighing and compounding. In New York, there are still two "licensed druggists"—individuals without a college education who, until 1928, could obtain a license to operate a pharmacy in a town with not more than 1,000 inhabitants.

In Arkansas, there are 160 "practical druggists" still in practice. They must be supervised by a registered pharmacist for 40 hours a week, but in the absence of the registered pharmacist—and for any hours in excess of 40 per week that the pharmacy may be open—they may fill prescriptions without supervision.

Illinois allows assistant pharmacists to work alone a minority of the hours that the pharmacy is open.

In addition, 15 States grant licenses to a person other than a registered pharmacist, or to a store other than a pharmacy, to sell patent medicines or household remedies. Three States require that such individuals be three miles from the nearest registered pharmacist, one State sets the distance at five miles, and another sets it at eight.

Dispensing Physicians. In all States except Nevada, which has omitted any reference to them in pharmacy laws, licensed practitioners of medicine are specifically exempted in the legislation defining the practice of pharmacy. The medical licensure act of seven States authorizes a physician to sell drugs and dispense prescriptions. Other States, however, have established certain limitations:

—In Arizona, New Mexico, and Utah, physicians may dispense only emergency drugs for their own patients.

—In California, Oregon, Rhode Island, and Texas, physicians may not operate a pharmacy, but physicians may operate such an establishment anywhere in Mississippi, in a town of 800 or less in North Carolina, and a town of 1,000 or less in Virginia.

—Virginia physicians without a pharmacy license are not permitted to sell drugs, although they may dispense to their own patients. In many States, a general prohibition limits such dispensing to a physician's own patients.

Qualifications of the Pharmacy

Except in Tennessee, Texas, Virginia, and the District of Columbia, the equipment for a qualified pharmacy is defined in State rules and regulations. A minimum standard for technical equipment and stock has been suggested by the National Association of Boards of Pharmacy.

In 36 States, specifications have been established for the physical layout of the pharmacy in terms of access, square feet of space, refrigeration facilities, and sanitation.

In a few States, there are rules regulating the location and operation of the pharmacy.

—In Montana, pharmacies may not be located in supermarkets, self-service stores, or similar establishments.

—In Maine, they may not be adjuncts or subsidiaries of other businesses.

—In South Dakota, they may not be operated on a self-service basis.

Different rulings have been set in other States.

—In the District of Columbia, there is no law requiring that a registered pharmacist be present, but it is practically impossible to operate a pharmacy without one because of the law governing the display of signs.

—In the majority of States, pharmacies may be owned by those who are not registered pharmacists providing a registered pharmacist serves as manager. North Dakota specifically requires that only a registered pharmacist may own a pharmacy, and Michigan stipulates that 50 percent of the stock of a pharmacy must be owned by a pharmacist.

—Several States set a minimum number of hours—ranging from 40 to 80 per week—that the pharmacy must be open. In Florida, the pharmacy department must be open at least 60 percent of the hours that the entire establishment is open. In Georgia, it must be 100 percent of the time.

—In 23 States, the prescription department must be locked when the registered pharmacist is absent, or a sign displayed to indicate that the prescription department is closed.

Regulations on Prescriptions

Records. In 32 States, a record must be kept of all prescriptions—for five years in 21 States, for two years in eight, for three years in two, and for an indefinite time in another.

Only 19 States call for a record of the dates of all refills. Such a record must be kept for two years in New Jersey and for five years in Hawaii.

Oral Prescriptions. Oral prescriptions may be accepted only by a registered pharmacist or an intern in nine States, while in other States this matter is not specifically mentioned.

Refills. A few States require special authorization for refills, particularly when they are more than a year old. Some States have regulations governing the giving or filling of copies of prescriptions; in some States, such copies may be filled, while in others this is specifically prohibited.

Substitution. Substitution of a drug or brand of drug different from that prescribed by the physician is specifically prohibited in the pharmacy laws or rules and regulations of 47 States, but there are no written rules against it in Alaska, Missouri, the District of Columbia, or Vermont. In the District and Vermont, however, the license of the pharmacist may be revoked for substitution, on the grounds that it is unethical conduct.

Label Typing. By their legal definitions of compounding and dispensing, California, Colorado, Nevada, and Ohio have made it mandatory for the pharmacist, himself, to type the label to be placed on the prescription bottle or container.

Mail Order Dispensing. Of the 15 States that mention the mail order business, only Alabama permits it and then only if the firm is registered with the State Board of Pharmacy and employs a pharmacist registered in the State of Alabama. Elsewhere, the regulations are quite different.

—The Mississippi Board of Pharmacy is charged with regulating "the clandestine traffic in prescription drugs through unauthorized channels" such as mail order firms.

—In Arizona, Massachusetts, Pennsylvania, and New Mexico, mail order dispensing is prohibited because it allegedly violates the physician-pharmacist-patient relationship.

—In Illinois, Michigan, and Oklahoma, it is illegal to dispense through the mail any drugs for which the prescriptions were received by mail.

—Out-of-State operators must have an Iowa pharmacy license in order to dispense drugs via the mails in that State.

—Minnesota pharmacists may not accept or fill a prescription received by mail and written by a physician not licensed to practice in Minnesota.

—The North Carolina Board of Pharmacy will not issue a pharmacy license if the distribution of drugs is to be by mail.

—Only an Ohio physician may prescribe and only a pharmacist registered in Ohio and employed in a pharmacy licensed in Ohio may dispense for an Ohio citizen.

—Minnesota, South Dakota, Vermont, and Washington prohibit the mail-order sale of drugs by prescription whenever such a sale has been solicited by advertising of any kind.

Even though these regulations are in existence, it appears that enforcement is difficult or impossible in most cases, and there has been little interruption to interstate mail-order dispensing.

Pickup Stations. Authorizing an individual or an agency to act as a pickup station for a prescription or a drug is illegal in 16 States. In Colorado, certain persons may be authorized to pick up and deliver prescriptions where pharmacy services are not available.

Vending Machines. Although most States prohibit the use of vending machines to dispense drugs, several permit their use under the supervision of a registered pharmacist. In some instances use of these machines under the supervision of a registered pharmacist is specifically permitted in a hospital.

Confidentiality. The pharmacy laws of 15 States require the pharmacist to consider confidential any information that he receives in performing his professional duties, and to reveal it only to appropriate authorities. General laws of many of the States also bear on the confidentiality of privileged documents.

Advertising

Various restrictions have been set up in most States to prevent the advertising of prescription drugs or their prices to the general public. In some instances, the prohibition is written into State law. In others, it is based on regulations promulgated by the State Board of Pharmacy. In addition, almost half of the States have laws prohibiting any advertising by a pharmacy which intimates professional superiority in any way.

The legal status of provisions outlawing prescription drug price advertising—especially when the prohibition is established by a State Board of Pharmacy rather than a State legislature—is not clear. In one reported court test of such a prohibition, the Florida Supreme Court held that such a regulation put forth by the pharmacy board was invalid. Following the court decision, the Florida legislature enacted an express prohibition into law; this is now being tested in the Florida courts. In Ohio, on the other hand, prescription drug advertising is considered legal, although it is not widely used.

In recent years, it has been proposed—notably by representatives of the Pharmaceutical Manufacturers Association—that State laws and regulations against prescription drug advertising should be abolished, and, in fact, that pharmacies should be encouraged to advertise the prices of prescription drugs. Such a step, it was claimed, would encourage price competition at the local level, and help to reduce the retail costs of prescriptions.

This proposed move has been opposed by the American Pharmaceutical Association, on the grounds that it would damage the professional status of pharmacists (*9*). The National Association of Retail Druggists has pointed out "that a variety of business, customer, and professional services have an effect on prescription drug prices in a retail establishment, and it is grossly misleading for the public to assume that these services are constant and that they should only shop for price." (*40*)

In the limited areas in which prescription drug prices have been advertised to the public in recent years—such as in Florida and Ohio—there is no clear evidence that this has had any particular influence in stimulating competition in the community or lowering drug prices.

Prescription Blank Advertising. In 16 States, prescription blanks bearing the name of a pharmacy or a pharmacist are not allowed. In Maine, pharmacies may distribute prescription blanks bearing only the name of the physician.

Trading Stamps. Only West Virginia and Pennsylvania make specific mention of trading stamps in their State pharmacy laws. Both prohibit their use with prescriptions.

Sales Tax

Differences in State sales tax laws are obvious:

- Six States have no sales tax laws of any kind.
- Twenty-five States tax all drugs, but several of these are considering repeal of the tax on prescription drugs.
- In eight States and the District of Columbia, nearly all drugs are exempt.
- In eight others, over-the-counter items are taxed, but prescription drugs are exempt.

Federal Laws

Some Federal legislation governs prescription drugs in general, and depressant and stimulant drugs and narcotics in particular. The Federal Food, Drug, and Cosmetic Act, for example, covers adulteration and misbranding of drugs, new drugs, antibiotics, and insulin.

The Durham-Humphrey Amendment, Section 503, requires that certain drugs be dispensed only upon a written prescription of a practitioner licensed by law, or by an oral prescription which is immediately reduced to writing and filed. Authorization for a refill may be either written, or oral if it is immediately reduced to writing and filed.

Legislation governing depressant and stimulant drugs and narcotics is more specific and extensive. Stock records of depressant and stimulant drugs and records of disposition must be kept for three years and made available to properly authorized personnel upon request. Prescriptions for such drugs may not be filled or refilled more than six months after the date on which the prescription was issued, and may not be refilled more than five times without a new prescription or new authorization. Similarly, records of narcotic drugs must be kept for two years. Certain drugs which "possess relatively little or no addiction liability" may be dispensed upon an oral prescription which is reduced to writing and filed for two years. Those who deal with narcotic drugs formerly were required to register annually with the Secretary of the Treasury.

On April 8, 1968, the Bureau of Narcotics was transferred from the Treasury Department to the newly created Bureau of Narcotics and Dangerous Drugs in the Justice Department. The FDA's Bureau of Drug Abuse Control was also transferred to the new bureau.

Fair Trade

The maintenance of resale price—known commonly as "fair trade"—is applied when manufacturers or suppliers agree with a retailer or other distributor that he will not resell their product below a certain fixed price to the consumer.

Such an agreement would eliminate price competition and therefore be considered illegal under the Sherman Act. The Miller-Tydings Act and the McGuire Act, however, amended the antitrust laws so that they do not apply to resale price maintenance agreements in any State where these are covered by an appropriate State law.

At present, 38 States have such statutes. In 21 of them, the statutes have nonsigner provisions which allow anyone to sue to prevent any retailer from knowingly selling below the "fair trade" price if at least one retailer in the State agrees with the manufacturer not to do so.

The present status of these laws is as follows:[a]

In 18 States, the Supreme Courts have declared their respective "fair trade" statutes constitutional, fully valid, and enforceable:

Arizona.
California.
Connecticut.
Delaware.
Illinois.
Tennessee.
Maryland.
Massachusetts.
Mississippi.
New Hampshire.
New Jersey.
Virginia.
New York.
North Carolina.
Ohio.
Rhode Island.
South Dakota.
Wisconsin.

In three States, there has been no State Supreme Court decision on the validity of their "fair trade" statutes, thereby leaving these statutes fully valid and enforceable:

Idaho[a]
Maine
North Dakota

In 17 States, the State Supreme Courts have declared only the nonsigner provision of the State's "fair trade" statute invalid:

Arkansas.
Colorado.
Florida.
Georgia.
Indiana.
Iowa.
Kentucky.
Louisiana.
Michigan.
Minnesota.
New Mexico.
Oklahoma.
Oregon.
Pennsylvania.
South Carolina.
Washington.
West Virginia.

In three States, the State Supreme Courts have held the entire "fair trade" statute invalid:

Alabama.
Montana.
Wyoming.

In five States and Puerto Rico, the legislatures have repealed the entire "fair trade" statute:

Hawaii.
Kansas.
Nebraska.
Nevada.
Utah.
Puerto Rico.

No "fair trade" legislation has ever been enacted in four States and the District of Columbia:

Alaska.
Missouri.
Texas.
Vermont.
District of Columbia.

Regardless of the legal status of the "fair trade" laws, however, it appears—even in those States in which their validity has been upheld by the State courts—they are not being enforced to any considerable extent, and their impact on the retail price of prescription drugs is minimal.

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[a] Source: U.S. Department of Justice, Personal Communication, 1967.

[a] A lower court has invalidated the nonsigner provision.

CHAPTER 19

THE NEW ROLE OF PHARMACY

Today, the stereotyped role of the pharmacist is seen as that of a man in a white coat counting tablets, typing labels, and calculating the price. One commentator has said:

> "There are those in the profession who practice it as a retail business, adhering to the philosophy that as the drug passes through my hands, I should get something for handling the merchandise." (*31*)

On the other hand, this same observer has noted that there could be a different role for the pharmacist:

> "There are those who are equally certain that the process of supplying a drug is a mechanical and collateral act remote from the drug information specialist who is more properly concerned with the selection of the right drug and its pharmacological effect." (*31*)

The possibility that pharmacists might assume the role of drug information specialist—rather than performing tasks which in many instances could be done better and more economically by machine—is currently exciting increased interest among those who see pharmacists taking a new and important part in the total health team.

To those who support such a concept, it is apparent that much of the traditional training still being given to pharmacists is no longer relevant, but that pharmacists possess many skills which have a strong potential for application in modern health care.

Number of Pharmacists. The number of pharmacists in active practice has increased from 101,630 in 1950 to 122,421 in 1967, but the annual rate of increase has not kept pace with population growth. This occupational time lag, coupled with the increased use of prescription drugs, might indicate a shortage of pharmacists. The lack of pharmacies in many hospitals is likewise used as an indication of a shortage in pharmacist manpower. Such a shortage, however, is difficult to demonstrate.

Of the licensed pharmacists currently in practice, about 85 percent are active in community pharmacies. (*26*) (The proportion in 1962 was 91 percent.) About seven percent are hospital pharmacists nearly five percent are engaged in manufacturing or wholesaling, and the remainder—about three percent—are employed in educational, governmental, and other institutions.

Among those in community pharmacy practice, many work in establishments which fill only five to ten prescriptions per day. Thus, they spend the greater part of their time in retail activities which may be only remotely related to consumer health. In some metropolitan areas, several pharmacies may exist within the same area, and the number of prescriptions each fills daily may be minimal.

It may be hypothesized that—if a highly educated pharmacist must supplement his income by routine retail functions in order to practice his profession—there is no substantial unfilled need for his professional services. Therefore, there may be no shortage of pharmacists in terms of the economic facts in the retail drug trade.

Education of Pharmacists. Any evaluation of the suitability of modern pharmacists for their present duties, and of their competence for different roles, requires an assessment of their educational training, particularly the considerable variation in length of training.

From available information, it appears that seven percent of those now in practice were not graduated from any of the 72 accredited schools of pharmacy in the United States. They were granted licenses after completion of brief, concentrated courses—usually lasting six months—and for prolonged periods as apprentices and assistant pharmacists. The last of the six-month schools closed in 1949.

Nine percent were graduated from a school of pharmacy after a two-year academic program and another nine percent graduated after completing a three-year program. The remainder—about three-fourths—have received academic training of four years or more.

In recent years, the pharmacy curriculum has begun to change in content as well as length. Traditionally, the program was directed toward the physical sciences, with major emphasis placed on the compounding techniques employed in the preparation of prescriptions, with relatively little time spent on the biological sciences, and scant attention was paid to the clinical condition and needs of the patient. Now a concern is being expressed about the need of pharmacists to understand the nature of disease processes, and the effect of drugs on these processes.

All schools of pharmacy now require a minimum of five years of college training before graduation with a B.S. degree in pharmacy. The University of Southern California and the University of California both require a minimum of six years before graduation, with each giving the professional degree of Doctor of Pharmacy (Pharm. D.). Other schools are considering extension of their programs to six years.

The Changing Practice of Pharmacy. There is, however, little agreement on the future role of the pharmacist—and on the education he must obtain to achieve new goals.

On the one hand, a former Commissioner of the Food and Drug Administration, and a physician himself, has voiced the view that the modern pharmacist is—or should be—"a vital bridge between the good physician and the renewed patient. He is a professional person for whom the ultimate goal is successful treatment of the human. He takes part in that treatment by knowing, through clinical training, and experience, the actions of drugs in the human."

Such a therapy advisor would be one who "knows how people react to drugs. He knows how people use—overuse, abuse, or misuse—drugs. And he knows how to advise them on the wise and effective use of drugs." (*17*)

Some hospitals, especially those in major medical center complexes, already use pharmacists as therapy advisors. They serve not only as drug dispensers, but also as sources of drug information for physicians, interns, residents, nurses and patients, often making ward rounds with the staff. In this role, pharmacists are beginning to utilize some of their previously unused skills, but at the same time they are demonstrating some of the deficiencies in their previous education, and their lack of clinical training. Pharmacy schools are responding to these deficiencies, even though they are responding late.

In one medical group on the West Coast, an experiment is underway to bring the therapy advisor, a person knowledgeable in pharmacology and chemistry, into an outpatient clinic setting. (*23*) In addition to providing the usual dispensing services, the clinic pharmacist will consult with the medical staff on drug therapy, review all patient medications in order to maximize therapeutic benefits and minimize undesirable side-effects, discuss the prescribed drug therapy with each patient, and be responsible for seeing all drug detail men, relieving the physicians of this time-consuming function.

In the foregoing examples, recognition of a potential new role for the pharmacist is in part a tacit admission that many practicing physicians—faced with a deluge of drugs numbering in the thousands—are unable to keep up with technical developments in this field.

Such an attitude is obviously counter to the traditional view held by many physicians. An official of the American Medical Association has expressed the view that pharmacists:

> ". . . can play a larger role on the health team by accepting responsibility as pharmacists . . . rather than by trying to place themselves in the role of therapeutic advisor to physicians. . . . If a pharmacist is to be trained as an effective therapeutic advisor, a man for all seasons, his training would have to duplicate that of the physician." (*39*)

The Future of Pharmacy. These disparate views pose several interesting problems:

- Will pharmacists, individually or through their professional associations, seek to develop a new role for all pharmacists which many of them—by virtue of educational deficiencies—are not now fitted to occupy?

- Will pharmacy schools be willing and able to break with tradition and develop new curricula, aimed at training graduates to accept these new responsibilities—to be full-time health professionals rather than retailers practicing a modest amount of pharmacy?

- Will physicians, in general, decline to accept an appropriately trained pharmacist as a member of the health team to serve as a source of up-to-date drug information, while at the same time be willing to accept advice from a detail man whose opinions may be somewhat colored by commercial interests?

A physician has said that change is already taking place:

> "Acceptance of the pharmacist as a vital member of the health team in clinical medicine is very close to being an accomplished fact, wherever pharmacy has put its best efforts forward." (*17*)

Others believe that implementation of such changes may alter the status and function of the community pharmacy.

> "It appears to me unlikely that the practice of pharmacy will continue to exist within the confines of the corner retail store. It is too expensive an operation. We don't need the store. We need the man. We need to place him as near as possible to the patient, to the physician, to the testing apparatus and on the decisional level of patient care." (*31*)

If "the man" is needed—the highly skilled man, trained to accept new responsibilities—then a decision must be made on whether such an individual can properly be employed in the routine task of dispensing—counting tablets, typing labels, and calculating the price. There is no evidence that it takes five or six years of college education to undertake such chores. Some pharmacy educators are already looking forward to developing a new type of less highly educated health manpower—the pharmacist aide—who can carry out these tasks.

Whether or not these and similar changes will be instituted are matters which may be speeded or impeded by professional or other pressures, but the final decision will eventually be determined, not by the traditional attitudes of one professional group or another, but by the dictates of the consumer's health needs.

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